FDA Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Disclaimers:

Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

The FOIA case report information may include both Electronic Submissions (Esubs) and Report Images (Non-Esubs). Case ID(s) will be displayed under separate cover pages for the different submission types.

Esub Case ID(s) Printed:

9681215 10511270 10511962

Run by: **STEPPERH**

Date - Time: **04-NOV-2016 08:34 AM**

Total number of cases (Esub): 3

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9681215

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CAN **Event Date:** **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 11-Nov-2013 **Mfr Rcvd Date:** 07-Nov-2013 **Mfr Control #:** CA-ASTRAZENECA-2013SE82130 **Application #:** 018240

Patient Information:

Age: 40 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	ATENOLOL			Oral				
2	CAMPRAL			Unknown				
3	CREATINE			Unknown				
4	EPHEDRINE HYDROCHLORIDE			Unknown				
5	ETHANOL			Unknown				
6	HOMEOPATHICS			Unknown				
7	HYDRASHRED			Unknown				
8	HYLANDS TEETHING TABLETS			Unknown				
9	LITHIUM CARBONATE			Unknown				
10	PANTOPRAZOLE			Unknown				
11	RAPID LEAN			Unknown				
12	RIPPED FREAK			Unknown				
13	SEROQUEL			Oral				
14	SUPER VITA VIM			Unknown				
15	VITAMIN B1			Unknown				
16	VITAMIN D			Unknown				

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9681215

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
17	WELLBUTRIN XL			Unknown				
18	XENADRINE EFX			Unknown				

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	ATENOLOL		NA	NA				ZENECA
2	CAMPRAL		NA	NA				
3	CREATINE		NA	NA				
4	EPHEDRINE HYDROCHLORIDE		NA	NA				
5	ETHANOL		NA	NA				
6	HOMEOPATHICS		NA	NA				
7	HYDRASHRED		NA	NA				
8	HYLANDS TEETHING TABLETS		NA	NA				
9	LITHIUM CARBONATE		NA	NA				
10	PANTOPRAZOLE		NA	NA				
11	RAPID LEAN		NA	NA				
12	RIPPED FREAK		NA	NA				
13	SEROQUEL		NA	NA				ZENECA
14	SUPER VITA VIM		NA	NA				
15	VITAMIN B1		NA	NA				
16	VITAMIN D		NA	NA				
17	WELLBUTRIN XL		NA	NA				

Case ID: 9681215

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
18	XENADRINE EFX		NA	NA				

Event Information:

Preferred Term (MedDRA Â© Version: 17.0)	ReC
Antipsychotic drug level above therapeutic	NA
Drug interaction	NA
Toxicity to various agents	NA

Event/Problem Narrative:

A report had been received from a health professional via health Canada concerning a 40 year old male patient.Medical history and concomitant medications of the patient were not reported.The patient had been receiving oral Atenolol (atenolol) started on an unknown date, oral seroquel (quetiapine fumarate) started on an unknown date, unknown campral (acamprosate calcium) started on an unknown date, unknown creatine (creatine) started on an unknown date, unknown ephedrine hydrochloride (ephedrine hydrochloride) started on an unknown date, unknown ethanol (ethanol) started on an unknown date, unknown hoodia (homeopathic nos) started on an unknown date, unknown hydrashred (no match) started on an unknown date, unknown hydroxycut (no match) started on an unknown date, unknown pantoprazole (pantoprazole) started on an unknown date, unknown pms-lithium carbonate (lithium carbonate) started on an unknown date, unknown rapid lean (no match) started on an unknown date, unknown ripped freak (no match) started on an unknown date, unknown super vita vim (vitamins nos) started on an unknown date, unknown vitamin B1 (thiamine hydrochloride) started on an unknown date, unknown vitamin D (ergocalciferol) started on an unknown date, unknown wellbutrin XL (bupropion hydrochloride) started on an unknown date and unknown xenadrine (acetylcarnitine, citrus aurantium, ephedra spp., Levothyroxine, pantothenic acid, paullinia cupana, salix alba, zingiber officinale) started on an unknown date.It was reported that the patient experienced drug interaction (preferred term: drug interaction), toxicity to various agents (preferred term: toxicity to various agents) and antipsychotic drug level above therapeutic (preferred term: antipsychotic drug level above therapeutic).Action taken with all interacting drugs was not applicable.The following products were considered to be interacting: atenolol, seroquel, campral, creatine, ephedrine hydrochloride, ethanol, hoodia, hydrashred, hydroxycut, pantoprazole, pms-lithium carbonate, rapid lean, ripped freak, super vita vim, vitamin b1, vitamin d, wellbutrin xl and xenadrine.The patient died from the event of drug interaction, toxicity to

Case ID: 9681215

various agents and antipsychotic drug level above therapeutic on an unspecified date.An autopsy performed was unknown.The reporter considered the events drug interaction, toxicity to various agents and antipsychotic drug level above therapeutic to be serious due the serious criteria of death.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No **Sender Organization:** ASTRAZENECA **503B Compounding Outsourcing Facility?:**

Case ID: 9681215

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 10511270

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** **Outcomes:** HO, **Application Type:** NDA

FDA Rcvd Date: 10-Oct-2014 **Mfr Rcvd Date:** 03-Oct-2014 **Mfr Control #:** US-PFIZER INC-2014275842 **Application #:** 019833

Patient Information:

Age: 3 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	INFANT ADVIL CONCENTRATED DROPS				UNK	Teething		
2	BABY ORAJEL NIGHTTIME FORMULA				UNK	Teething		
3	BABY ORAJEL TEETHING PAIN MEDICINE				UNK	Teething		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	INFANT ADVIL CONCENTRATED DROPS		Unk	NA				PFIZER
2	BABY ORAJEL NIGHTTIME FORMULA		Unk	NA				
3	BABY ORAJEL TEETHING PAIN MEDICINE		Unk	NA				

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Dyspnoea	NA
Eye movement disorder	NA
Moaning	NA

Case ID: 10511270

Event/Problem Narrative:

This is a spontaneous report from a contactable consumer. A 3-year-old male patient of an unspecified ethnicity started to receive ibuprofen (INFANT ADVIL CONCENTRATED DROPS), benzocaine (BABY ORAJEL TEETHING PAIN MEDICINE), HYLAND TEETHING TABLETS, and benzocaine (BABY ORAJEL NIGHTTIME FORMULA) via an unspecified route of administration from an unspecified date to an unspecified date at unspecified doses for teething. Medical history included Kawasaki's disease from (b) (6) and they used scalpel to deliver her son and they were able see where a little tissue had built up where the scalpel had entered his skin but did not enter his brain. It was kind of in between the scalp and the skull. She stated his head was oddly shaped. Concomitant medication included ibuprofen (CHILDREN'S ADVIL). It was reported the patient experienced eyes rolling in back of head and moaning like a Down's Syndrome sort of sound from when he started teething to age 3 years. He also quit breathing a few times for a few seconds. The son is now 5 years old. Mother states the son was taken to the hospital for a bunch of tests and did not receive answers for his experiencing these episodes. The patient underwent lab tests and procedures which included computerised tomogram head results of which were unknown, skull x-ray the results of which were unknown and MRI the results were unknown. The action taken in response to the events for ibuprofen and benzocaine was unknown.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Kawasaki's disease	(b) (6)		UNKNOWN
Head deformity			
Incision site complication			

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
CT brain scan	Unknown				N
Head X-ray	Unknown				N
MRI	Unknown				N

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 10511270

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	CHILDREN'S ADVIL			UNK				

Reporter Source:

Study Report?: No

Sender Organization: PFIZER

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 10511962

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 19-Sep-2014 **Outcomes:** OT, **Application Type:** NDA

FDA Rcvd Date: 19-Feb-2015 **Mfr Rcvd Date:** 09-Feb-2015 **Mfr Control #:** US-PFIZER INC-2014274670 **Application #:** 019833

Patient Information:

Age: 1 YR **Sex:** Female **Weight:** 9 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Infant Advil Concentrated Drops		.625 ML/	Oral	0.625 ml, UNK	Fever		
2	BABY ORAJEL TEETHING PAIN MEDICINE				UNK			
3	Infant Advil Concentrated Drops		1.25 ML/		1.25 ml, UNK	Sore throat	19-Sep-2014	01-Oct-2014

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Infant Advil Concentrated Drops		Unk	NA	R14186			PFIZER
2	BABY ORAJEL TEETHING PAIN MEDICINE		Unk	NA				
3	Infant Advil Concentrated Drops		Unk	NA				PFIZER

Event Information:

Preferred Term (MedDRA Version: 17.1)	ReC
Choking	NA
Eye movement disorder	NA
Head deformity	NA
Hypoaesthesia	NA
Local swelling	NA
Moaning	NA
Musculoskeletal stiffness	NA

Case ID: 10511962

Preferred Term (MedDRA © Version:	18.0	ReC
Pyrexia		NA
Seizure		NA
Vomiting		NA

Event/Problem Narrative:

This is a spontaneous report from a contactable consumer on behalf of her daughter. A 13-month-old Caucasian female patient started to receive ibuprofen (INFANT ADVIL CONCENTRATED DROPS), Drug lot number R14186, Expiration date eb2017), oral from an unspecified date at a dose of 0.625 ml and 1.25 ml from 19Sep2014 to 01Oct2014 for fever and sore throat and HYLAND'S TEETHING TABLETS , via an unspecified route of administration at 2 tablets to 03Sep2014 for teething, and benzocaine (BABY ORAJEL TEETHING PAIN MEDICINE), via an unspecified route of administration from an unspecified date to an unspecified date at an unknown dose and frequency for an unspecified indication. Medical history included kawasaki's disease from 09Sep2014 to an unknown date and ear infection from 03Sep2014 to an unknown date. Concomitant medication included amoxicillin since 03Sep2014 5 mg orally twice a day for ear infection, stopped on 09Sep2014 due to yeast infection, paracetamol (LITTLE REMEDIES FOR FEVERS) 1.25 ml for fever since 03Sept2014. Caller states that her daughter has been taking ADVIL 8 hr infant medication since she was born and it works great. Caller reports that daughter has had: bumps coming up on her head since May2014. Caller says she is not able to get clear answers from the doctors. Mother did not provide daughter's height. Caller reports that on 19Sep2014 her daughter's eyes were rolling back in her head, and the doctors say that it is seizures. Caller says she thinks it could be fever related that daughter may have had seizure. The baby was stiff as a board, moaning, had extremely high temperature on 19Sep2014. Caller states her daughter received 9 oz formula and a small amount of baby food and threw it all up on 19Sep2014, and 1.25ml ADVIL 8H infant medicine was given about an hour later because she was really hot, but did not know what her temperature was. Caller says she was doing some research to try and figure out if mixing the ADVIL 8h Infant with HYLAND'S BABY TEETHING TABLETS and/or ORAJEL daytime and ORAJEL night time was causing problems that her daughter was experiencing. Mother states she notices her daughters episodes after she has given ADVIL and 2 teething tablets, but only when adding a teething agent with the ADVIL. Mother also states her son experienced similar symptoms with eyes rolling in back of head and moaning from when he started teething to age 3. The son is now 5 years old. Mother states the son was taken to the hospital for a bunch of tests and did not receive answers for his experiencing these episodes. Suspect Medications: ADVIL 8h infant: NDC number not seen on box. ADVIL 8h infant dose 0.625 ml Physician recommend dosage of 1.25 ml due to her weight, but has been administering a smidge over .625ml. Other medications: AMOXICILLIN 5mg orally twice a day, gave it to her sometimes once a day, started on 03Sep2014 to treat the ear infection, stopped on 09Sep2014 due to a bad yeast infection. Mother states only two dates had both AMOXICILLIN and ADVIL 8H infant on 08SEP2014 and 09SEP2014. LITTLE REMEDYS FOR FEVERS, instant fever pain reliever

Case ID: 10511962

last dose 03sept2014 1.25 ml, for fever. BABY ORAJEL mother states this numbed her throat and choked her, and felt not healthy to give it to her so after that 1 time I never gave it to her again. Mother states she has noticed bumps coming up on her head since May2014. Mother states the doctors do not know why and she is just trying to get some answers. On 24Sep2014, the baby had soft area on side of back of head. On 25Sep2014, the baby had soft spot fifty cent size piece on back right side of head. 06May2014 mother states huge whole side of head swelling. Mother states physician thought child had bumped her head. When the mother saw the regular doctor with her daughter the mother reports the regular doctor said the child did not hit her head, as would have to be a hard hit to make that happen. The patient underwent lab tests and procedures which included body temperature: 101.5 on 18Sep2014, body temperature: 102.5 on 29Sep2014, body temperature: 100 on 29Sep2014, body temperature: 100 on 03Oct2014, computerised tomogram head: scalp hematoma on 06May2014. CT scan of Brain: (06May2014) Findings: no mass or midline shift, no acute hemorrhaging, skull unremarkable, minimal mucousal thickening, impression: normal enhanced CT scan of the Brain, paranasal sinus disease. Most suggestive of scalp hematoma, no solid or cyst soft tissue tumor could be identified, there is a compressible fluid collection in right side of the scalp. Mother states there is a MRI scheduled for 04Oct2014. Outcome of all events not reported. The physician reported that the patient did not provide information regarding the reported adverse event with the use of the product. The action taken in response to the events for ibuprofen was unknown was permanently withdrawn on 01Oct2014, for HYLAND'S TEETHING TABLETS was permanently withdrawn on 03Sep2014, and for benzocaine was permanently withdrawn on an unspecified date. The outcome of the events was unknown. This physician denied the patient provide information regarding the reported adverse event with the use of product and could not confirm the occurrence of the events reported by the patient.

Follow-up (22Dec2014): New information received from a contactable physician including physician comment.

Follow-up (09Feb2015): New information from a contactable Physician includes: medical confirmation status.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Ear infection	03-Sep-2014		UNKNOWN
Kawasaki's disease	09-Sep-2014		UNKNOWN

Medical History Product(s)	Start Date	End Date	Indications	Events
AMOXICILLIN	03-Sep-2014	09-Sep-2014	Ear infection	Yeast infection

Case ID: 10511962

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Body temperature	101.5				N
Body temperature	100				N
CT brain scan	scalp hematoma				N
Body temperature	102.5				N
Body temperature	100				N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	LITTLE REMEDIES FOR FEVERS	1.25 ML/		1.25 ml, UNK	Fever	03-Sep-2014		17 DAY

Reporter Source:

Study Report?: No

Sender Organization: PFIZER

503B Compounding Outsourcing Facility?:

Literature Text:

Printer: CDPEDQ5
User: STEPPERH
Date - Time: 04-Nov-2016 08:36 AM
Total Number of Cases (Non-Esub): 123
Total Number of Pages: 563
Print Job Number: 12985

Disclaimers:
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Processed Case Id's for Images:

9275207 9305621 9314081 9316714 9325460 9325466 9341721 9341729
9341740 9341747 9342328 9342345 9342356 9342360 9410155 9412421
9412536 9412646 9412659 9412660 9412682 9412689 9412695 9424540
9461703 9471241 9486434 9570361 9570446 9622302 9627012 9630574
9661367 9747541 9767440 9790085 9820308 9924670 9998991 9999086
10023432 10024252 10027923 10040722 10149861 10162192 10162223 10234825
10234831 10257359 10267562 10272692 10272885 10275530 10283615
10285322 10285323 10302306 10302334 10302341 10302641 10307987 10313881
10314685 10359541 10384035 10387468 10390459 10395246 10402276
10412341 10430246 10436018 10436103 10483550 10486049 10486072 10501178
10510040 10519215 10529024 10529055 10530766 10530771 10530789
10542710 10542735 10542775 10542937 10542971 10543066 10547547 10567790
10570064 10576562 10584800 10589980 10601392 10619563 10619580
10627664 10631888 10638399 10642973 10643083 10648706 10648708 10656951
10678285 10678309 10678313 10684780 10691018 10723317 10792549
10855443 10862441 10866401 10877680 10901130 10945484 10984052 10993411

Failed Case Id's for Images:

Total Failed Cases: 0

Individual Case Safety Report

9275207-01-00-01

CDER

OTC

CaseID: 9275207

Form approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

VOLUNTARY reporting of events, product problems and product use errors

Internet Submission - Page 1/2

...Safety Information and Adverse Event Reporting Program

FDA USE ONLY

Triage unit sequence # 510829

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 3 Months	☐ Female ☑ Male	13 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/31/2012	04/30/2013

5. Describe Event, Problem or Product Use Error

After giving my son the 2 tablets per hour for 3 doses -the label says you can give up to 2 tablets for 6 hours-, he became extremely lethargic to the point of being unresponsive. His eyes glazed over and remained opened but he would not make eye contact and looked like he was in a daze. When I put him on my knees he began to slide off almost involuntarily. He was not moving. I rushed him to the ER and his heart rate was low but after a few minutes improved. The doctor said it was possibly from the belladonna in this product. After getting home, I found out it has been recalled in the past for very similar reactions. My son is okay now, but

More

6. Relevant Tests/Laboratory Data, Including Dates

Not sure how to do lab test but I saved bottle in case you can

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

None

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hyland's baby Teething Tablets — Hyland's

#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets/hr	3 hrs	po
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)

#1 One day 03/31/2013 -- 03/31/2013

#2 --

4. Diagnosis or Reason for Use *(Indication)*

#1 Teething

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 115731	#1
#2	#2

9. NDC # or Unique ID

54973-3127-2

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address

(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☑ Manufacturer ☐ User Facility ☑ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

DSS MAY 01 2013

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

had I given him 3 more doses every hour -totaling 6 doses in 6 hours as label says-, I shudder at the thought of what could have happened to him. Clearly they still have problems with inconsistent dosing as they did the last time they were recalled. This product is dangerous and needs to be pulled off the market.

Individual Case Safety Report

9305621-01-00-01

CDER

OTC

CaseID: 9305621

Form approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

OLUNTARY reporting of
vents, product problems and
product use errors

Internet Submission - Page 1

Adverse Event Reporting Program

FDA USE ONLY

Triage unit sequence # 512921

A. PATIENT INFORMATION

1. Patient Identifier: Baby Boy - (b) (6) in confidence
2. Age at Time of Event, or Date of Birth: (b) (6) 6 Months
3. Sex: ☐ Female ☑ Male
4. Weight: 13 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   ☐ Death: ____ *(mm/dd/yyyy)*
   ☐ Disability or Permanent Damage
   ☐ Life-threatening
   ☐ Congenital Anomaly/Birth Defect
   ☑ Hospitalization - initial or prolonged
   ☐ Other Serious (Important Medical Events)
   ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*: 10/02/2012
4. Date of this Report *(mm/dd/yyyy)*: 05/21/2013

5. Describe Event, Problem or Product Use Error

My son, who is now 13 months old, had some unexplained seizure activity for a span of about 3 months. The events started when he was 6 months old. Recently I came across information that there has been a link to seizure activity. I used Hyland Teething tablets during this time quite frequently. My son had a very rough time teething and these seemed to help. Unfortunately I am now concerned that in trying to help ease my son's pain that I inadvertantly cause other medical issues. I still have the same bottle of tablets that I used in October.

More

6. Relevant Tests/Laboratory Data, Including Dates

3 day hospital stay with a 48 hour EEG on (b) (6) Follow up EEG in (b) (6) when more episodes occured. Multiple other seizure episodes without hospital stay because the doctors said that unless they lasted greater than 15 minutes that we should just wait the episode out at home. One

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Unexplained rash brakouts during this time as well. His whole body would break out in a hive.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland Teething Tablets — Hyland
   #2

2. Dose or Amount / Frequency / Route
   #1 2-3 tablets / 4 times daily / po
   #2

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 10/01/2012 -- 11/01/2012
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 teething
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
   #1 115007
   #2

7. Expiration Date
   #1
   #2

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID: 54973-3127-2

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

CTU

MAY 22 2013

4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #

5. Operator of Device
   ☐ Health Professional
   ☐ Lay User/Patient
   ☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

MAY 22 2013

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional? ☐ Yes ☑ No
3. Occupation
4. Also Reported to:
   ☐ Manufacturer
   ☐ User Facility
   ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

B6. Relevant tests/laboratory data, including dates continued

episode happened at church where a pediatrician witnessed my son's demeanor and health directly after the episode.

Individual Case Safety Report

CaseID: 9314081

9314081-01-00-01

CDER

VOLUNTARY reporting of adverse events, product problems and product use errors

Submission - Page 1/3

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence # 313207

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event, or Date of Birth: (b) (6) 16 Months
3. Sex: [x] Female [ ] Male
4. Weight: 23.6 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. [x] Adverse Event [x] Product Problem (e.g., defects/malfunctions)
[x] Product Use Error [x] Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

[x] Death: ____ (mm/dd/yyyy)
[x] Life-threatening
[x] Hospitalization - initial or prolonged
[x] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
[x] Disability or Permanent Damage
[x] Congenital Anomaly/Birth Defect
[x] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 07/26/2010

4. Date of this Report (mm/dd/yyyy): 05/23/2013

5. Describe Event, Problem or Product Use Error

We have video of several episodes posted on (b) (6) They are private and you would need to contact me for access. We were using baby orajel and night time baby orajel when we ended up in the hospital for a week due to my daughters eyes rolling in to the back of her head and turning blue around her lips. They couldn't figure out what was going on and determined that she was having seizures and thought that the blue around her mouth may have been being caused by sucking on her binkie. They sent us home with an anti-seizure drug but could not figure out what could have caused a perfectly normal 16 month old to start having the issues she was

More

6. Relevant Tests/Laboratory Data, Including Dates

(b) (6) low bun 7 (b) (6) high chloride 109 (b) (6) low creatinine .26 (b) (6) high reactive lymphocyte 4

More

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

allergy to penicillin, white, pregnancy is n/a she is only 4, no one smokes in our home or around (b) (6) no one drinks, she doesn't have liver,

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

[ ] Yes [x] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Baby Orajel Benzocaine 7.5% CHURCH & DWIGHT

#2 Baby Orajel Nighttime Benzocaine 10% CHURCH & DWIGHT

	2. Dose or Amount	Frequency	Route
#1	pea size	4 x daily	po
#2	pea size	4 x daily	po

3. Dates of Use (If unknown, give duration) from/to (or best estimate)

#1 07/10/2010 -- 09/05/2010

#2 07/10/2010 -- 09/05/2010

4. Diagnosis or Reason for Use (Indication)

#1 teething pain

#2 teething pain

5. Event Abated After Use Stopped or Dose Reduced?

#1 [x] Yes [ ] No [ ] Doesn't Apply

#2 [x] Yes [ ] No [ ] Doesn't Apply

6. Lot #

#1

#2

7. Expiration Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 [ ] Yes [ ] No [x] Doesn't Apply

#2 [ ] Yes [ ] No [x] Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Orajel

2. Common Device Name

CTU

3. Manufacturer Name, City and State

MAY 24 2013

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	[ ] Health Professional [x] Lay User/Patient [ ] Other:
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

[ ] Yes [ ] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

MAY 24 2013

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

Phone (b) (6)

E-mail (b) (6)

2. Health Professional? [ ] Yes [x] No

3. Occupation: Consumer/Non-Health

4. Also Reported to:
[x] Manufacturer
[x] User Facility
[x] Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: [x]

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

having. She was on the anti-seizure meds for about 2-3 weeks as we were seeking a second opinion as the meds were not working. We met with nuro at (b) (6) (b) (6) and she said pull her off all meds I want a new eeg a week after all meds are out of her system. We took her off the meds and by day 3 she was having less eye rolling and by the day of the eeg it happened once that day. We NEVER put her back on the anti-seizure drug because her eeg was normal and the doc said we didn't need to. We also NEVER gave her orajel again. with in a month no more eye rolling and no more blue around her lips. She is an amazing health little girl and this stuff needs to be labeled and dispensed responsibly. We had no idea that this was the cause of her issue we just stopped everything and here years later I find an article that describes exactly what we were going through with our own baby.

B7. Other relevant history, including preexisting medical conditions continued

kidney or other issues.

DSS
MAY 24 2013

Individual Case Safety Report

9316714-01-00-01

1/3

OTC

CaseID: 9316714

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

VOLUNTARY reporting of events, product problems and product use errors

Internet Submission - Page 1 CDER

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY

Triage unit sequence # 513409

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 20 Months	☐ Female ☑ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/30/2013	05/26/2013

5. Describe Event, Problem or Product Use Error

I have been giving my son hylands teething tablets since he was 6 months old. I have noticed some things that I did not like after giving my son hylands teething tablets. My son would seem aggitated, he would start shaking his body every once in a while, and also, my son does not talk real good, he is delayed in motor skills, and speech, and at times, cannot keep his balance. These problems are still ongoing and reacuring with my son. - At 19 1/2 months of age, My son was teething so I gave him hylands teething tablets. Later, my son's body started shaking and then he fell to teh floor with his body still shaking. His eyes were open but I

More

6. Relevant Tests/Laboratory Data, Including Dates

- Different events have happened with my son after taking hylands teething tablets since he was 6 months old -tremors, aggitation, not being able to sleep, delayed speech, delayed motor skills, not being able to keep his balance, seizures, shortness of breath. *ALL EVENTS HAPPENED AFTER I GAVE

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

*On-going appointments for my son's seizures, and speech/motor skills delays due to hylands teething tablets. * Because this product is still on

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething Tablets Not Available Not Available
#2

2.	Dose or Amount	Frequency	Route
#1	2 teething tablets	when needed	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 05/01/2011 -- 05/25/2013 (two years)
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 Not Available
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
Not Available

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hylands Teething Tablets

2. Common Device Name
Not Available

CTU

3. Manufacturer Name, City and State
Purchased teething tablets in (b) (6)

MAY 28 2013

4. Model #	Lot # Not Available	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

MAY 28 2013

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

My son will have on going therapy for delays in speech and motor skills. He also, will be seeing a neurologist on Friday May 31, 2013. I will be conta

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

B5. Describe event or problem continued

couldn't seem to get my son to snap out of what looked like a seizure. I picked up my phone and when I was about to dial 911, my son stopped shaking and was able to be responsive. He had peed himself. He was crying and very freaked out. I took him to the ER and found out that my son infact, had a seizure. Two days later, I followed up with his pediatrician. His pediatrician refered us to a neurologist. We see the neurologost Friday May 31, 2013.

B6. Relevant tests/laboratory data, including dates continued

MY SON HYLANDS TEETHING TABLETS* (b) (6) -19 1/2 months old-, my son had a seizure. Took him to the ER and they confirmed it. - May 1st, 2013 -19 1/2 months old-, my son had to see a development coordinator due to delayed motor skills and delayed speech - May 2nd, 2013 - 19 1/2 months old-, follow up with pediatrician due to seizure and ER visit. - May 23rd, 2013 - 20 1/2 months old-, My son started seeing his speech/motor skills therapist due to delays. He has to see this therapist once a week now. - May 31, 2013 -20 1/2 months old-, My son will be seeing a neurologist for tremors and seizures.

DSG

MAY 28 2013

B7. Other relevant history, including preexisting medical conditions continued

the shelves and because hylands teething tablets have cause delays and seizures with my son, I am seeking legal action and will be talking with a lawyer/attorney and will be seezing further actions.

DSS

MAY 28 2013

F. Other (Concomitant) medical products continued

cting his pediatrician and a lawyer/attorney on Friday May 31, 2013 about the hylands teething tablets and what it has done to my son and to take further action.

DSS

MAY 28 2013

Individual Case Safety Report

9325460-01-00-01

CDER

OTC

CaseID: 9325460

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

OLUNTARY reporting of
events, product problems and
product use errors

Internet Submission - Page 1/2

The FDA Safety Information and
Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 513867

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 9 Months	☐ Female ☑ Male	17 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☑ Product Use Error ☑ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☑ Death: ____ *(mm/dd/yyyy)*
☑ Life-threatening
☑ Hospitalization - initial or prolonged
☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☑ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
05/11/2013	05/30/2013

5. Describe Event, Problem or Product Use Error

After using teething gel, child had seizures and twitching

More

6. Relevant Tests/Laboratory Data, Including Dates

Child taken by ambulance to ER on (b) (6) follow-up with primary care provider on 05/13/2013, pediatric neurologist 05/14/2013, EEG 05/14/2013, hospital admit (b) (6) abnormal labs not directly pertaining to positive alkaloids of belladonna poisoning but does show consequence of using the

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

No health concerns prior *Death did not occur, box needed to be checked to proceed*

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylan's Teething Gel 0.0000003% belladonna Hyland's Baby
#2

2.	Dose or Amount	Frequency	Route
#1	¼ ribbon on finger	prn	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 04/28/2013 -- 05/19/2013
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 ndc 54973-7521
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
54973-7521-2

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland's Baby CTU

2. Common Device Name
Teething Gel

3. Manufacturer Name, City and State
Hyland's Inc., Los Angeles CA 90061
MAY 31 2013

4. Model #	Lot # 120936c	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

DSS

MAY 31 2013

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Other Health	☑ Manufacturer ☑ User Facility ☑ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B6. Relevant tests/laboratory data, including dates continued

teething gel, 72HR EEG starting on (b) (6) MRI with contrast/ under anesthesia (b) (6)
After countless hours in the doctor, on the phone with the doctor/ neurology, hospital and research online, data suggests the teething gel proves to fit symptoms of belladonna poisoning

DSS

MAY 31 2013

Individual Case Safety Report

9325466-01-00-01

CDER

OLUNTARY reporting of
vents, product problems and
product use errors

The FDA Safety Information and
Adverse Event Reporting Program

Internet Submission - Page 1

CTC CaseID: 9325466

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence # 513863

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
18 months In confidence	18 Months	☐ Female ☑ Male	25 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/18/2012	05/30/2013

5. Describe Event, Problem or Product Use Error

Have used Hyland teething tablets as needed and per instructions since my son started teething in June of 2011. He was completely unconscious on (b) (6) and taken by ambulance to the ER. He was unconscious and not moving or responding for four hours straight. The dr said he'd had a seizure.

CTU

MAY 31 2013

More

6. Relevant Tests/Laboratory Data, Including Dates

In er in (b) (6) at (b) (6) medical center.. CT scan, MRI, EKG, etc. on (b) (6)

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

No previous health problems or medical history. Very healthy toddler.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland teething tablets Regular Hyland
#2

2.	Dose or Amount	Frequency	Route
#1	1-2 tablets	As needed	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 06/24/2011 -- 10/01/2012
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething pain relief
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hylands Baby
2. Common Device Name: Teething tablets
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☑ Other: Mom--me-

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☑ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
MAY 31 2013

Phone # | E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Case Safety Report

CaseID: 9341721

9341721-01-00-01

OTC

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event:	3. Sex	4. Weight
In confidence	6 Months or Date of Birth:	☑ Female ☐ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: (mm/dd/yyyy)
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
00/00/2009	05/22/2013

5. Describe Event or Problem

GRANDDAUGHTER HAD A BLOOD CLOT ON HER BRAIN WITH SEIZURES. TOOK HER TO BE TESTED. DOCTORS NOT SURE WHAT IT WAS DUE TO. LEFT SCAR TISSUE ON HER BRAIN. WAS USING TEETHING TABLETS AT THE TIME BUT NOT SURE HOW MANY OR HOW OFTEN. WANTS TO KNOW IF TEETHING TABLETS CAUSED THE INJURY.

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN TESTS CONDUCTED.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNKNOWN. NO FEVER. NO RECENT VACCINATIONS. NO INJURY TO HEAD. NOT A PRE-MIE. NO OTHER MEDICATIONS AT THE TIME.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeled)*

#1 HYLAND'S TEETHING TABLETS

#2

Received JUN 07 2013 CDR

2. Dose, Frequency & Route Used

#1 UNKNOWN DOSAGE

#2

3. Therapy Dates *(If unknown, give duration)* *(from/to or best estimate)*

#1

#2

4. Diagnosis for Use *(Indication)*

#1 TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1

#2

7. Exp. Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS JUN 07 2013 USA

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

JUN 06 2013

PLEASE TYPE OR USE BLACK INK

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number** 310-768-0700
3. **Report Source** *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 05/22/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)** BLOOD CLOT, SEIZURES
9. **Manufacturer Report Number** 54973 RAE052213EF002

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. **Device Manufacture Date** *(mm/yyyy)*
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Evaluation Codes** *(Refer to coding manual)* Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS
JUN 07 2013

JUN 06 2013

9341721-01-00-03

(CONTINUATION PAGE)
For use by user-facilities,
s, distributors, and manufacturers
for MANDATORY reporting

MEDWATCH

FORM FDA 3500A (6/10) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
JUN 07 2013

JUN 06 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

C[illegible]9341721

Hylands

SECTION I: COMPLAINT

COMPLAINT #: RVD052213EF002

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/22/13

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.: DOESN'T HAVE ANYMORE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GRANDAUGHTER HAD A BLOOD CLOT ON HER BRAIN WITH SEIZURES. TOOK HER TO BE TESTED. DOCTORS NOT SURE WHAT IT WAS DUE TO. LEFT SCAR TISSUE ON HER BRAIN. WAS USING TEETHING TABLETS AT THE TIME BUT NOT SURE HOW MANY OR HOW OFTEN. WANTS TO KNOW IF TEETHING TABLETS CAUSED THE INJURY. PATIENT CONTINUES TO HAVE SEIZURES. GRANDMOTHER DID NOT HAVE VERY DETAILED INFORMATION TO PROVIDE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9341721-01-00-04

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICES RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE052213EF002

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/22/13

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWatt

DATE: 05-28-13

DSS JUN 07 2013

BY: N/A

QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

JUN 06 2013

CaseID: 9341721

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE052213EF002 **COMPLAINT #:** RVD052213EF001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

Individual Case Safety Report

9341721-01-00-05

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 05-28-13

DSS
JUN 07 2013

BY: N/A DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUN 07 2013

Individual Case Safety Report

9341729-02-00-01

CaseID: 9341729

OTC

For use by user-facilities, distributors and manufacturers
MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973 see page 2

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (6/10)

Page 1 of 4

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	1 Years	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
00/00/2009	05/23/2013

5. Describe Event or Problem

GAVE 1 TABLET AS NEEDED FOR TEETHING IN 2009. MOTHER DOES NOT KNOW IF THERE WAS A TIME CONNECTION BETWEEN GIVING TEETHING TABLETS AND SEIZURES. CHILD WAS DIAGNOSED WITH FEBRILE CONVULSIONS. CHILD DID HAVE FEVERS AT THE TIME OF SEIZURES. CHILD HAS NOT HAD A SEIZURE IN QUITE A WHILE.

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN TESTS CONDUCTED

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

MOTHER HAS SEIZURES RESULTING FROM HEAD TRAUMA.
PATIENT'S BROTHER HAS SEIZURES ALSO.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 1 TABLET AS NEEDED	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS

SEP 09 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

SEP 06 2013

Individual Case Safety Report

CaseID: 9341729

9341729-02-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # _____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code _____ – _____ – _____; Device Code _____ – _____ – _____
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 05/22/2013
5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☑ Follow-up # 1
8. Adverse Event Term(s): SEIZURES / FEBRAL CONVULSIONS
9. Manufacturer Report Number: 54973 RAE052213EF001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: _____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method _____ – _____ – _____ – _____; Results _____ – _____ – _____ – _____; Conclusions _____ – _____ – _____ – _____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: _____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
SEP 09 2013

SEP 06 2013

Individual Case Safety Report

9341729-02-00-03

CaseID: 9341729

06-12-13 mlc

Article # 70081 000482898

STANDARD HOMEOPATHIC

May 23, 2013

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $ 5.69 per bottle. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $ 6.22

DSS
SEP 09 2013

Standard Homeopathic Company · Setting the Standard in Homeopathy, Since 1903
210 West 131st Street · Box 61067 · Los Angeles, CA 90061 · (213) 321-4284 · fax (310) 516-8579
P.O. Box 87 · Bryn Mawr, PA 19010 · (215) 520-0580 · fax (215) 520-0582

SEP 06 2013

Individual Case Safety Report

9341729-02-00-04

ER COMPLAINT RECORD

Case ID: 9341729

Hyland's

COMPLAINT #: RVD052213EF001

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/22/13

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.: DOESN'T HAVE

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GAVE 1 TABLET AS NEEDED FOR TEETHING IN 2009. SHE DOES NOT KNOW IF THERE WAS A TIME CONNECTION BETWEEN GIVING TEETHING TABLETS AND SEIZURES. CHILD WAS DIAGNOSED WITH FEBRILE CONVULSIONS. CHILD DID HAVE FEVERS AT THE TIME OF SEIZURES. CHILD HAS NOT HAD A SEIZURE IN QUITE A WHILE. MOTHER HAS SEIZURES AS A RESULT OF HEAD TRAUMA. MOTHER WANTS A REFUND FOR ONE BOTTLE. ALSO TOOK REPORT FOR CHILD'S BROTHER WHO HAS SEIZURES AND WHO USED BABY TEETHING TABLETS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

RECEIVED

SEP 06 2013

CDR

IF REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO OUR PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

05/22/13: PREPARED REFUND REQUEST TOTALING $ 6.22. 06/12/13: MAILED REFUND CHECK # 509375 TOTALING $ 16.26 ON ARTICLE # 70081830 000486289877.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6)

DATE: 05/23/13 & 06/11/13

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE052213EF001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/22/13

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 08-27-13

DSS SEP 09 2013

BY: N/A

QA / QC DIRECTOR

DATE:

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

SEP 06 2013

Individual Case Safety Report

CaseID: 9341740

9341740-01-00-01

OTC

For use by user facilities, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (6/10)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence

2. Age at Time of Event: 6 Months or Date of Birth:

3. Sex: [✓] Female [ ] Male

4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [✓] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death: ____ (mm/dd/yyyy)
- [ ] Disability or Permanent Damage
- [✓] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [ ] Hospitalization - initial or prolonged
- [✓] Other Serious (Important Medical Events)
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 00/00/2003

4. Date of This Report (mm/dd/yyyy): 05/22/2013

5. Describe Event or Problem

BACK IN 2003 FOR 6 MONTH CHECK-UP CHILD WAS AT THE DOCTOR'S OFFICE AND WHILE SHE WAS IN THE ROOM AFTER BEING WEIGHED THE CHILD TURNED BLUE AND HAD A SEIZURE. WAS ONLY USING TEETHING TABLETS AT THE TIME. WAS IN OFFICE FOR VACCINATIONS BUT DID NOT RECEIVE THEM YET. DOCTORS NOT ABLE TO DETERMINE CAUSE OF SEIZURES. CONTINUED TO HAVE SEIZURES - DROP SEIZURES DAILY AND GRAND MAL ONCE A MONTH. TAKES KEPRA FOR SEIZURES.

6. Relevant Tests/Laboratory Data, Including Dates

SPINAL TAP AND OTHER TESTS WITH INCONCLUSIVE RESULTS. NO FEVER AT THE TIME.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 DOESN'T REMEMBER
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

Received JUN 05 2013 CDR

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [✓] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: [ ] Health Professional [ ] Lay User/Patient [ ] Other:
Catalog # | Expiration Date (mm/dd/yyyy)
Serial # | Other #

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address (b) (6)

Phone # (b) (6)

DSS

JUN 06 2013

JUN 07 2013

USA

2. Health Professional? [ ] Yes [✓] No

3. Occupation

4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [●] Unk.

Individual Case Safety Report

CaseID: 9341740

9341740-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report: ☐ Initial ☐ Follow-up # ____

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ (mm/dd/yyyy)
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ (Specify)

13. Report Sent to Manufacturer?
☐ Yes ____ (mm/dd/yyyy)
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
05/22/2013

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 RAE052213EF003

8. Adverse Event Term(s)
SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes (Refer to coding manual)
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUN 07 2013

JUN 06 2013

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS

JUN 07 2013

JUN 06 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: RVD052213EF003

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/22/2013

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.: DOESN'T HAVE ANYMORE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: PURCHASED PRODUCT IN 2003. BACK IN 2003 FOR THE 6 MONTH CHECK-UP CHILD WAS AT THE DOCTOR'S OFFICE AND WHILE SHE WAS IN THE ROOM AFTER BEING WEIGHED THE CHILD TURNED BLUE AND HAD A SEIZURE. WAS ONLY USING THE TEETHING TABLETS AT THE TIME. WAS IN OFFICE FOR VACCINATIONS BUT DID NOT RECEIVE THEM YET. DOCTORS NOT ABLE TO DETERMINE CAUSE OF SEIZURES. CONTINUED TO HAVE SEIZURES – DROP SEIZURES DAILY AND GRAND MAL ONCE A MONTH. TAKES KEPRA FOR SEIZURES. NO FEVER AT THE TIME. WENT TO THE DOCTOR WHO CONDUCTED A SPINAL TAP AND OTHER TESTS WITH INCONCLUSIVE RESULTS. TOLD HER THAT SIDE EFFECTS DUE TO HOMEOPATHICS TEND TO BE TRANSIENT IN NATURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) N

PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE) N

Individual Case Safety Report

9341740-01-00-04

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (CIRCLE ONE) N

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE052213EF003

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/22/13 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWulff

DATE: 05-28-13 DSS JUN 07 2013

BY: N/A.
QA / QC DIRECTOR

DATE: JUN 06 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

JUN 06 2013

CaseID: 9341740

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE052213EF003 COMPLAINT #: RVD052213EF003

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

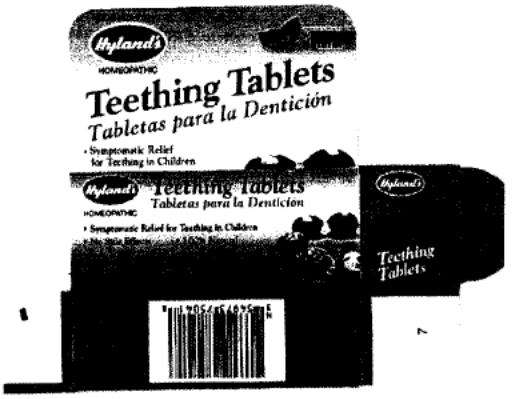
SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9341740-01-00-05

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 05-28-13

DSS
JUN 07 2013

BY: N/A
QA / QC DIRECTOR

DATE:
JUN 06 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 9341747

9341747-02-00-01

Form Approved: OMB No. 09 10-029 1, Expires12/31/11
See OMB statement on reverse.

For use by user-facilities, ters, distributors and manufacturers for MANDATORY reporting

Mfr Report # 5[illegible]3 502 page 2

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (6/10)

Page 1 of 10 of 105

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	2 Years or Date of Birth: (b) (6)	☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
12/23/2010	08/22/2013

5. Describe Event or Problem

SEIZURE ON (b) (6) CHILD HAD JUST TURNED 2 YEARS OLD. DOES NOT KNOW HOW MUCH OR HOW OFTEN SHE WAS GIVING TEETHING TABLETS. CAN'T REMEMBER HOW OLD WHEN SHE STARTED USING. WENT TO THE ER; HOSPITALIZED OVERNIGHT. X-RAYS AND MRI A FEW WEEKS LATER. TESTS WERE NORMAL. HAD ANOTHER SEIZURE IN (b) (6) BUT DOES NOT KNOW IF USING TEETHING TABLETS. DOCTOR DIAGNOSED AS FEBRILE SEIZURES. NO OTHER SEIZURES. WANTS A REFUND. HAS A FEVER OF 101F AFTER THE SEIZURE AT THE HOSPITAL. NO ALLERGIES. FULL TERM BABY.

6. Relevant Tests/Laboratory Data, Including Dates

X-RAYS AND MRI; TESTS WERE NORMAL.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO KNOWN ALLERGIES. FULL TERM BABY. HAD 101F AFTER THE SEIZURE AT THE HOSPITAL.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 UNKNOWN	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS
SEP 09 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

SEP 06 2013

Individual Case Safety Report

CaseID: 9341747

9341747-02-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
05/24/2013

5. (A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☑ Follow-up # 1

8. Adverse Event Term(s)
FEBRILE SEIZURES

9. Manufacturer Report Number
54973 RAE052413EF001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
SEP 09 2013

SEP 06 2013

Individual Case Safety Report

9341747-02-00-03

CaseID: 9341747

Article # 701
1830004862
9853

STANDARD HOMEOPATHIC

May 28, 2013

(b) (6)

Dear (b) (6)

Pursuant to your letter regarding our Hyland's Teething tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $ 5.69. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $ 6.22

DSS
SEP 09 2013

Standard Homeopathic Company · Setting the Standard in Homeopathy, Since 1903
210 West 131st Street · Box 61067 · Los Angeles, CA 90061 · (213) 321-4284 · fax (310) 516-8579
P.O. Box 87 · Bryn Mawr, PA 19010 · (215) 520-0580 · fax (215) 520-0582

SEP 06 2013

Individual Case Safety Report

9341747-02-00-05

CUSTOMER COMPLAINT RECORD

Case ID: 9341747

Hyland's

COMPLAINT #: RVD052413EF001

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/24/13

PRODUCT: HYLAND'S TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.: DOESN'T HAVE PURCHASED IN 2010

REPORTER: (b) (6)

ADDRESS: (b) (6)

RECEIVED
SEP 06 2013
CDR

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SEIZURE ON (b) (6) CHILD HAD JUST TURNED 2 YEARS OLD. DOES NOT KNOW HOW MUCH OR HOW OFTEN SHE WAS GIVING TEETHING TABLETS. CAN'T REMEMBER HOW OLD WHEN SHE STARTED USING. WENT TO THE ER; HOSPITALIZED OVERNIGHT. X-RAYS AND MRI A FEW WEEKS LATER. TESTS WERE NORMAL. HAD ANOTHER SEIZURE IN (b) (6) BUT DOES NOT KNOW IF USING TEETHING TABLETS. DOCTOR DIAGNOSED AS FEBRILE SEIZURES. NO OTHER SEIZURES. WANTS A REFUND. HAS A FEVER OF 101°F AFTER THE SEIZURE AT THE HOSPITAL. NO ALLERGIES. FULL TERM BABY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/24/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

05/28/13: PREPARED REFUND REQUEST TOTALING $ 6.22. 06/12/13: MAILED REFUND CHECK # 509377 TOTALING $ 6.22 ON ARTICLE # 700818300004 86289853.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6)

DATE: 05/28/13 & 06/12/13

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE052413EF001

ADVERSE EVENT SERIOUS: (Y) / N

DSS
SEP 09 2013

ADVERSE EVENT REPORTED ON: 05/24/13

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 08-27-13

BY: N/A
QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

SEP 06 2013

Individual Case Safety Report

9342328-02-00-01

OTC

CaseID: 9342328

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse

...y user-facilities,
...utors and manufacturers
ATORY reporting

Mfr Report # 54973

UF/Importer Report #

FORM FDA 3500A (6/10)

Page 1 of 18

CDER

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	3 1/2 Months	☐ Female	____ lbs
In confidence	or Date of Birth:	☑ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
05/05/2013 - 05/10/2013	05/29/2013

5. Describe Event or Problem

TOOK BABY TEETHING TABLETS 3 TIMES ON 05/5/13. MAY 5, 2013 CHILD STARTED SHAKING AT APPROXIMATELY 6:45 PM, WAS ALERT AND SHOOK FOR 30 SECONDS. FROM 05/05 - 05/07 HAS 3 MORE SHAKING EPISODES. 05/10/13 MOTHER GAVE 2 BABY TEETHING TABLETS AND 30 MINUTES LATER CHILD HAD SHAKING EPISODE. DOCTORS DIAGNOSED SHAKING EPISODES AS SEIZURES. NO EPISODES SINCE 05/10/13.

Received

AUG 22 2013

CDR

6. Relevant Tests/Laboratory Data, Including Dates

MEDICAL TESTS WERE NORMAL.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 2TABS 3 TIMES; 2 TABS PM	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 112723	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone # (b) (6)
(b) (6)	

DSS

AUG 23 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	AUG 22 2013	☐ Yes ☐ No ◉ Unk.

Individual Case Safety Report

CaseID: 9342328

9342328-02-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy):
7. Type of Report: ☐ Initial ☐ Follow-up # _____
8. Date of This Report (mm/dd/yyyy):
9. Approximate Age of Device:
10. Event Problem Codes (Refer to coding manual): Patient Code _____ Device Code _____
11. Report Sent to FDA? ☐ Yes _____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: _____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes _____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply): ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 05/29/2013

5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #:

7. Type of Report (Check all that apply): ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☒ 15-day ☒ Follow-up # 1

8. Adverse Event Term(s): SEIZURES

9. Manufacturer Report Number: 54973 AE # 1383

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code:
4. Device Manufacture Date (mm/yyyy):
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes (Refer to coding manual): Method _____ Results _____ Conclusions _____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
AUG 23 2013

AUG 22 2013

Individual Case Safety Report

9342328-02-00-03

TINUATION PAGE)
: by user-facilities,
butors, and manufacturers
DATORY reporting

FORM FDA 3500A (6/10) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
AUG 23 2013

AUG 22 2013

Individual Case Safety Report

9342328-02-00-04

Case ID 9342328 mld

article # 701

1830004862B

9846

May 29, 2013

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $ 9.19. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $ 10.04

DSS
AUG 23 2013

Standard Homeopathic Company · Setting the Standard in Homeopathy, Since 1903
210 West 131st Street · Box 61067 · Los Angeles, CA 90061 · (213) 321-4284 · fax (310) 516-8579
P.O. Box 87 · Bryn Mawr, PA 19010 · (215) 520-0580 · fax (215) 520-0582

AUG 22 2013

Individual Case Safety Report

9342328-02-00-06

CaseID: 9342328

COMPLAINT RECORD

Hyland's

COMPLAINT #: 2333

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/23/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: 112723

REPORTER: (b) (4)

ADDRESS:

CITY:

STATE: (b) (4)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (4)

E-MAIL:

NATURE OF COMPLAINT: ON MAY 5, 2013, GAVE 2 TABLETS OF BABY TEETHING TABLETS IN AM, NOON, AFTERNOON. CUSTOMER CALLED ON 05/24/13. MAY 5, 2013 CHILD STARTED SHAKING AT APPROXIMATELY 6:45 PM. CHILD WAS ALERT, SHOOK FOR 30 SECONDS. FROM 05/05 – 05/07 HAD 3 MORE EPISODES. TOOK HIM TO THE DOCTOR AND SAID HE LOOKED FINE. 05/10/13: SAW A NEUROLOGIST WHO SAID CHILD WAS FINE. DID TEST MEASUREMENTS AND ALL WAS FINE. 05/10/13 PM MOTHER GAVE 2 TABLETS AND 30 MINUTES LATER CHILD HAD A SHAKING EPISODE. DOCTORS CALLED SHAKING EPISODES "SEIZURES". HAS NOT USED BABY TEETHING TABLETS SINCE 05/10/13. NO SHAKING EPISODES / SEIZURES SINCE 05/10/13. WANTS A REFUND FOR ONE BOTTLE OF BABY TEETHING TABLETS (135 COUNT). TOLD HER TO DISCUSS CAUSES FOR SYMPTOMS WITH DOCTORS. NO FEVER ON MAY 5. NOT ILL ON MAY 5, CHILD WAS FULL-TERM BABY. NO NEW FOODS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/23/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

05/29/13: PREPARED REFUND REQUEST TOTALING $ 10.04.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6)

DATE: 05/29/13

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1383

DSS

AUG 23 2013

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/23/13

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-04-13

BY:

QA / QC DIRECTOR

DATE: 06-04-13

AUG 22 2013

cc: QA / QC Production

Individual Case Safety Report

CaseID: 9342328

9342328-02-00-07

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1383 **COMPLAINT #:** 2333

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

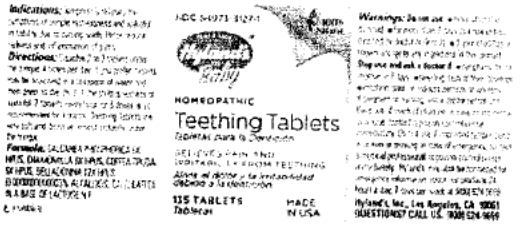
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

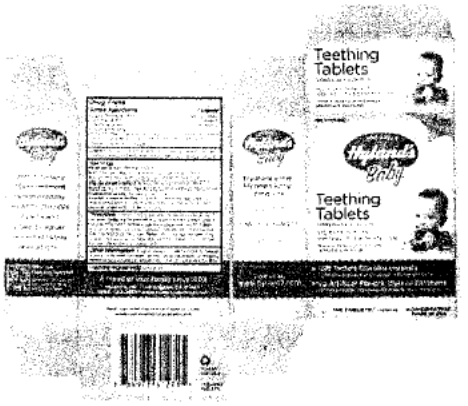
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
AUG 23 2013

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: DATE:
QA / QC DIRECTOR

AUG 22 2013

9342328-02-00-08

COMPLAINT RECORD

CaseID: 9342328

COMPLAINT #: 2333

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/23/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: 112723

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: ON MAY 5, 2013, GAVE 2 TABLETS OF BABY TEETHING TABLETS IN AM, NOON, AFTERNOON. CUSTOMER CALLED ON 05/24/13. MAY 5, 2013 CHILD STARTED SHAKING AT APPROXIMATELY 6:45 PM. CHILD WAS ALERT, SHOOK FOR 30 SECONDS. FROM 05/05 – 05/07 HAD 3 MORE EPISODES. TOOK HIM TO THE DOCTOR AND SAID HE LOOKED FINE. 05/10/13: SAW A NEUROLOGIST WHO SAID CHILD WAS FINE. DID TEST MEASUREMENTS AND ALL WAS FINE. 05/10/13 PM MOTHER GAVE 2 TABLETS AND 30 MINUTES LATER CHILD HAD A SHAKING EPISODE. DOCTORS CALLED SHAKING EPISODES "SEIZURES". HAS NOT USED BABY TEETHING TABLETS SINCE 05/10/13. NO SHAKING EPISODES / SEIZURES SINCE 05/10/13. WANTS A REFUND FOR ONE BOTTLE OF BABY TEETHING TABLETS (135 COUNT). TOLD HER TO DISCUSS CAUSES FOR SYMPTOMS WITH DOCTORS. NO FEVER ON MAY 5. NOT ILL ON MAY 5, CHILD WAS FULL-TERM BABY. NO NEW FOODS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

Received

AUG 22 2013

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

CDR

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/23/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

05/29/13: PREPARED REFUND REQUEST TOTALING $ 10.04. 06/12/13: MAILED REFUND CHECK # 509378 TOTALING $ 10.04 ON ARTICLE # 70081830 00486289846.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (4)

DATE: 05/29/13 & 06/12/13

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1383

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/23/13

BY: EDYTA FRACKIEWICZ

DSS

AUG 23 2013

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 08-06-13

BY: QA / QC DIRECTOR

DATE: 08-05-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

AUG 22 2013

FORM # VD1

Individual Case Safety Report

9342345-02-00-01

CDER

CaseID: 9342345

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

user-facilities,
tors and manufacturers
TORY reporting

Mfr Report # 54973
UF/Importer Report #
FDA Use Only

FORM FDA 3500A (6/10)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: 2 1/2 Years or Date of Birth:	3. Sex ☐ Female ☑ Male	4. Weight ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
01/00/2012	05/23/2013

5. Describe Event or Problem

GAVE 1 TABLET 1 1/2 YEARS AGO WHEN NEEDED. HAD A SEIZURE INJANUARY 2012. HAD SEVERAL SEIZURES SINCE THEN. HAD AN EEG AND MRI; ALL ARE NORMAL. NOT DUE TO FEVERS. HAD A COUPLE THAT THEY THOUGHT WERE FEVER INDUCED BUT SOME WERE NOT. CHILD HAS NOT HAD A SEIZURE IN 3 - 4 MONTHS. CHILD WOULD SHAKE, FALL UNCONSCIOUS, AND NOT BREATHE WHILE SEIZING.

6. Relevant Tests/Laboratory Data, Including Dates

EEG AND MRI. RESULTS WERE NORMAL.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

MOTHER HAS HISTORY OF SEIZURES DUE TO HEAD TRAUMA.
BROTHER HAS HISTORY OF FEBRILE CONVULSIONS.
CHILD HAS NO HEAD TRAUMA. NOT PREMATURE. NO MEDICATIONS FOR SEIZURES.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 1 TABLET AS NEEDED	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 RELIEVE TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 113207	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-31271-5

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS
AUG 23 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

AUG 22 2013

Individual Case Safety Report

CaseID: 9342345

9342345-02-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____; Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 05/22/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☒ 15-day ☑ Follow-up # 1
8. Adverse Event Term(s): SEIZURES
9. Manufacturer Report Number: 54973 AE # 1378

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method ____ - ____ - ____ - ____; Results ____ - ____ - ____ - ____; Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
AUG 23 2013

AUG 22 2013

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
AUG 23 2013

AUG 22 2013

9342345-02-00-04

OMPLAINT RECORD

6/5/13 Case # 700815 00048128 9754

COMPLAINT #: 2327

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/22/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: 113207

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GAVE 1 TABLET 1 ½ YEARS AGO WHEN NEEDED. HAD A SEIZURE IN JANUARY 2012. HAD SEVERAL SEIZURES SINCE THEN. HAD AN EEG, MRI. ALL ARE NORMAL. NOT DUE TO FEVERS. HAD A COUPLE THAT THEY THOUGHT WERE FEVER INDUCED BUT SOME WERE NOT. CHILD HAS NOT HAD A SEIZURE IN 3 – 4 MONTHS. CHILD WOULD SHAKE UNCONSCIOUS, AND NOT BREATHE WHILE SEIZING. SEND A REFUND FOR 1 BOTTLE. MOTHER HAS SEIZURES DUE TO HEAD TRAUMA. NO MEDICATIONS FOR SEIZURES. NOT PREMATURE. CHILD HAS NO HISTORY OF HEAD TRAUMA. BROTHER HAS HISTORY OF FEBRILE CONVULSIONS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 05/22/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

05/23/13: PREPARED REFUND REQUEST TOTALING $ 10.04.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6) DATE: 05/23/13

SECTION IV: ADVERSE EVENT REPORTS AE #: 1378

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/22/13 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

DSS AUG 23 2013

BY: QA / QC DIRECTOR DATE: 06-04-13

cc: QA / QC, Production, Packaging, Shipping / Receiving

Form # VD1

AUG 22 2013

Individual Case Safety Report

CaseID: 9342345

9342345-02-00-05

E EVENT DATA FORM

AE #: 1378

COMPLAINT #: 2327

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: QA / QC DIRECTOR DATE: 08-05-13

DSS AUG 23 201

DISTRIBUTION: FDA ADVERSE EVENT FILE

AUG 22 2013

9342345-02-00-06

COMPLAINT RECORD

Case ID 9342345

COMPLAINT #: 2327

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/22/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: [illegible]

RECEIVED
AUG 22 2013
CDR

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GAVE 1 TABLET 1 ½ YEARS AGO WHEN NEEDED. HAD A SEIZURE IN JANUARY 2012. HAD SEVERAL SEIZURES SINCE THEN. HAD AN EEG, MRI. ALL ARE NORMAL. NOT DUE TO FEVERS. HAD A COUPLE THAT THEY THOUGHT WERE FEVER INDUCED BUT SOME WERE NOT. CHILD HAS NOT HAD A SEIZURE IN 3 – 4 MONTHS. CHILD WOULD SHAKE UNCONSCIOUS, AND NOT BREATHE WHILE SEIZING. SEND A REFUND FOR 1 BOTTLE. MOTHER HAS SEIZURES DUE TO HEAD TRAUMA. NO MEDICATIONS FOR SEIZURES. NOT PREMATURE. CHILD HAS NO HISTORY OF HEAD TRAUMA. BROTHER HAS HISTORY OF FEBRILE CONVULSIONS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

05/23/13: PREPARED REFUND REQUEST TOTALING $ 10.04. 06/12/13: MAILED REFUND CHECK # 509375 TOTALING $ 16.26 ON ARTICLE # 70081830 000486289877.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6) DATE: 05/23/13 & 06/12/13

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1378

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/22/13 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: [signature] DATE: 08-06-13 DSS AUG 23 2013

BY: [signature] QA / QC DIRECTOR DATE: 08-05-13

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

AUG 22 2013

Individual Case Safety Report

9342345-02-00-07

CaseID: 9342345 08-12-13 M
Article # 70
1830 000486
9877

May 23, 2013

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $ 9.19 per bottle. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $ 10.04

DSS
AUG 23 2013

Standard Homeopathic Company · Setting the Standard in Homeopathy, Since 1903
210 West 131st Street · Box 61067 · Los Angeles, CA 90061 · (213) 321-4284 · fax (310) 516-8579
P.O. Box 87 · Bryn Mawr, PA 19010 · (215) 520-0580 · fax (215) 520-0582

AUG 22 2013

Individual Case Safety Report

CaseID: 9342356

9342356-01-00-01

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

or use by user-facilities, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 4 Months or Date of Birth:
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: ____ (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 04/00/2012 - PRESENT

4. Date of This Report (mm/dd/yyyy): 05/29/2013

5. Describe Event or Problem

05/24/13 INFORMATION OBTAINED FROM CUSTOMER: (b) (6) SON STARTED HAVING SEIZURES. USING BABY TEETHING TABLETS FOR ONE MONTH PRIOR TO THIS. NO FEVER AT THE TIME OF SEIZURE. SEIZURE IN 2012 CAUSED HIM TO LOSE OXYGEN TO BRAIN. WENT TO (b) (6) HOSPITAL AND WAS HOSPITALIZED FOR 2 1/2 - 3 WEEKS. UNDERWENT GASTRIC TUBE SURGERY SECONDARY TO OXYGEN LOSS TO BRAIN. SEIZURE PRESENTED AS SHAKING AND DROOLING FOR 1 MINUTE.

6. Relevant Tests/Laboratory Data, Including Dates

TESTS IN HOSPITAL (b) (6) MRI, X-RAY, SWALLOW STUDY, OBSERVATION AFTER EATING.

(b) (6) GASTRIC TUBE SURGERY

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CURRENT DIAGNOSIS: FAILURE TO THRIVE, EPILEPSY, APNEA, GERD.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 1 1/2TAB PO BID EOD X1MO
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-3137-3

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Catalog # | Expiration Date (mm/dd/yyyy)
Serial # | Other #

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

JUN 10 2013

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

DSS

E. INITIAL REPORTER

1. Name and Address

Phone # JUN 2013

USA

2. Health Professional? ☐ Yes ☐ No

3. Occupation

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☐ Unk.

JUN 07 2013

FDA USE ONLY

FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

MARK PHILLIPS
EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number** 310-768-0700
3. **Report Source** *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 05/22/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)** SEIZURES
9. **Manufacturer Report Number** 54973 AE # 1384

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. **Device Manufacture Date** *(mm/yyyy)*
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Evaluation Codes** *(Refer to coding manual)* Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS
JUN 10 2013

DSS
JUN 9 2013

JUN 07 2013

FORM FDA 3500A (6/10) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(For continuation of C.10 and/or D.11; please distinguish)*

DSS

JUN 10 2013

Other Remarks

DSS

JUN [redacted] 2013

JUN 07 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

C 9342356

SECTION I: **COMPLAINT**

COMPLAINT #: 2335

TAKEN BY: MARK PHILLIPS

DATE OF COMPLAINT: 05/22/13

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET—T135

SIZE: 135 TABLETS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: REPORTED READ ON INTERNET THAT TEETHING TABLETS CAUSE SEIZURES AND EPILEPSY IN INFANTS. REPORTER NOTED THE PRODUCT WAS TAKEN OFF THE SHELF AT WAL-MART A FEW DAYS AGO. REPORTER THEN STATED "MY SON IS NOW HAVING SEIZURES AND EPILEPTIC (SIC)". 05/24/13 FOLLOW-UP (EF): (b) (6) SON STARTED HAVING SEIZURES. USING BABY TEETHING TABLETS FOR ONE MONTH PRIOR. GIVING 1 ½ TABLETS BY MOUTH TWICE A DAY EVERY OTHER DAY FOR 1 MONTH. NO FEVER AT THE TIME OF SEIZURE. SEIZURE IN 2012 CAUSED HIM TO LOSE OXYGEN TO BRAIN. WAS SENT TO (b) (6) HOSPITAL AND WAS HOSPITALIZED FOR 2 ½ - 3 WEEKS. UNDERWENT GASTRIC TUBE SURGERY BECAUSE OF MEMORY LOSS 2° TO OXYGEN LOSS TO BRAIN. GOES TO OCCUPATIONAL THERAPY. DOCTOR'S NOT SURE WHY CHILD HAD SEIZURE. SEIZURE PRESENTED AS SHAKING AND DROOL FOR 1 MINUTE. TESTS IN HOSPITAL: MRI, X-RAY, SWALLOW STUDY, OBSERVATION AFTER EATING. DIAGNOSIS: FAILURE TO THRIVE, EPILEPSY, APNEA, GERD. MEDICINES: KEPRA 2ML EVERY MORNING; 2.5ML EVERY PM; CYPROHEPTADINE 1 TEASPOON EVERY DAY, PEPCID. WILL GO BACK TO NEUROLOGIST IN 2 WEEKS AND WILL ASK ABOUT USE OF BABY TEETHING TABLETS. DOES NOT WANT A REFUND. CHILD BORN 6-WEEKS PREMATURE. NO OTHER MEDICATIONS AT TIME OF SEIZURE. NO INJURY OR ILLNESS AT THE TIME. ALLERGIC TO AMOXICILLIN AND LATEX.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

NOTE: PHARMACIST RETURNED CALL AT 5:49PM AND 6:05 PM ON 05/22/13 AND 2:55PM ON 05/23/13 LEAVING DETAINED MESSAGE, REQUEST TO CALL BACK, AND RETURN PHONE NUMBER. CUSTOMER DID NOT RETURN CALL AS OF COMPLETION OF THIS REPORT ON 05/23/13 AT 3:30PM.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

RECEIVED
JUN 07 2013
CDR

SECTION II: **INVESTIGATION**

INVESTIGATION: NO LOT NUMBER. PROCEDURES ARE IN PLACE TO ENSURE PRODUCT QUALITY.

Individual Case Safety Report

9342356-01-00-04

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: MARK PHILLIPS

SECTION III: **CORRECTIVE ACTION:**

DSS
JUN 10 2013

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1384

ADVERSE EVENT SERIOUS: (Y) / N

DSS
JUN 2013

ADVERSE EVENT REPORTED ON: 05/22/13 BY: MARK PHILLIPS

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: QA / QC DIRECTOR DATE: 06-04-13

JUN 07 2013

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

CaseID: 9342356

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1384 COMPLAINT #: 2335

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

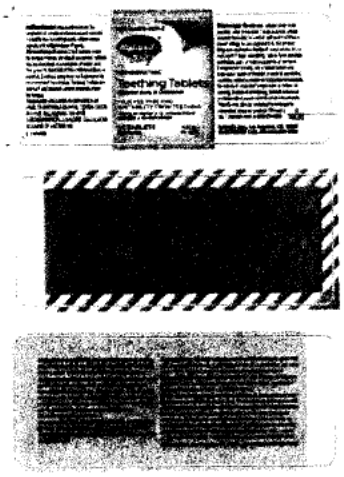
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

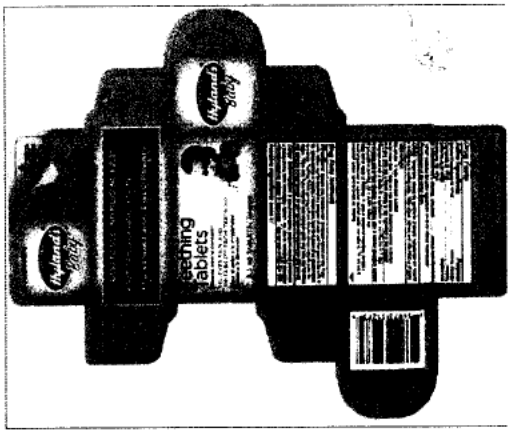
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

Individual Case Safety Report

9342356-01-00-05

DSS
JUN 10 2013

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

DSS
JUN 2013

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: DATE:
QA / QC DIRECTOR

JUN 07 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 9342360

9342360-01-00-01

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

or use by user-facilities, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 11 Months or Date of Birth:
3. Sex: [x] Female [ ] Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [ ] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- [ ] Death: ____ (mm/dd/yyyy)
- [ ] Life-threatening
- [x] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 12/00/2012

4. Date of This Report (mm/dd/yyyy): 05/24/2013

5. Describe Event or Problem

GAVE TEETHING TABLETS AND SOMETIME AFTER THAT CHILD EXPERIENCED CONVULSIONS WITH EYES ROLLING BACK OF HEAD, STIFFENING UP, WHEN SHE CAME TO SHE WOULD CRY AND TAKE DEEP BREATHS. WAS HOSPITALIZED FOR ONE WEEKEND IN (b) (6). DOCTOR THOUGHT THAT ELECTROLYTES COULD BE OFF. CONVULSIONS OCCURED IN HOSPITAL AND THEN NEVER HAPPENED AGAIN AND SHE NEVER USED PRODUCT AGAIN.

6. Relevant Tests/Laboratory Data, Including Dates

SPINAL TAP, EEG, CAT SCAN, MRI. DOCTORS COULDN'T SEE ANYTHING.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NO KNOWN ALLERGIES. FULL TERM PREGNANCY. NO OTHER MEDICATIONS AT THE TIME. NO FEVER.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2-3TABS//2-3X/DAY//1-2DY
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF OF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [x] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1 113995
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID
54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: [ ] Health Professional [ ] Lay User/Patient [ ] Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
JUN 10 2013

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

DSS
JUN 2013

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

JUN 07 2013
USA

2. Health Professional? [ ] Yes [x] No
3. Occupation
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [•] Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 9342360

9342360-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 05/23/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): CONVULSIONS
9. Manufacturer Report Number: 54973 AE # 1380

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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JUN 10 2013

DSS
JUN 2013

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9342360-01-00-03

(CONTINUATION PAGE)
For use by user-facilities,
...ers, distributors, and manufacturers
for MANDATORY reporting

MEDWATCH

FORM FDA 3500A (6/10) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

DSS

JUN 10 2013

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

DSS

JUN [redacted] 2013

Other Remarks

JUN 07 2013

CaseID: 9342360

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

9342360-01-00-04 Individual Case Safety Report

SECTION I: COMPLAINT

COMPLAINT #: 2329

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/23/13

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: 113995

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CHILD WAS 11 MONTHS OLD ON (b) (6) AND GAVE HER TEETHING TABLETS AND CHILD WOULD GET CONVULSIONS, EYES ROLLING BACK OF HEAD, STIFFENING UP. WHEN SHE CAME TO SHE WOULD CRY AND TAKE DEEP BREATHS LIKE SHE COULDN'T BREATHE. WENT TO THE HOSPITAL, DID A SPINAL TAPE. NO RESULTS. HAD AN EEG, CAT SCAN, AND MRI AND DOCTORS COULD NOT SEE ANYTHING. DOCTORS THOUGHT ELECTROLYTES COULD BE OFF. HOSPITALIZED FOR ONE WEEKEND IN (b) (6) GIVING 2 – 3 TABLETS UNDER TONGUE 2 – 3 TIMES A DAY FOR 1 OR 2 DAYS WHEN THIS HAPPENED. SEVERAL TIMES OVER THE COUPLE OF DAYS SHE WAS IN THE HOSPITAL IT HAPPENED. NEVER HAPPENED AGAIN. NEVER USED THE TEETHING TABLETS AGAIN. WANTS A REFUND FOR BABY TEETHING TABLETS (135 COUNT). NO KNOWN ALLERGIES. FULL TERM PREGNANCY. NO OTHER MEDICATIONS AT THE TIME. NO FEVER.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

RECEIVED
JUN 07 2013

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

CDR

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/23/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

DSS
JUN 10 2013

05/24/13: PREPARED REFUND REQUEST TOTALING $ 9.19.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6)

DATE: 05/24/13

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1380

DSS
JUN 10 2013

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/23/13 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-04-13 JUN 07 2013

BY:
QA / QC DIRECTOR

DATE: 06-04-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

CaseID: 9342360

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1380 **COMPLAINT #:** 2329

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)
ADDRESS:
CITY: STATE: (b) (6)
COUNTRY: USA ZIP CODE:
PHONE #: (b) (6)
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

Individual Case Safety Report

9342360-01-00-05

DSS
JUN 10 2013

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

DSS
JUN 2013

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: DATE:
QA / QC DIRECTOR

JUN 07 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

CaseID: 9410155

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

9410155-01-00-01

5FEC

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

Page 1 of 4

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	5 Years or	☐ Female ☒ Male	35 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
09/27/2010	11/02/2010

5. Describe Event or Problem

TOOK 1/4 OF THE BOTTLE ON 9/25 AND THEN ON (b) (6) WENT TO ER WITH DIFFICULTY BREATHING. RASH ON HIPS THAT STARTED AROUND THE SAME NIGHT AND IS STILL CONTINUING.

WENT TO ER. GIVEN STEROIDS TO HELP CHILD BREATHE; AQUAPHOR FOR THE RASH' UNKNOWN ANTI-ITCH CREAM.

ER PHYSICIAN'S DIAGNOSIS WAS CROUP; DOCTOR DIDN'T SEE THE RASH.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 1/4 BOTTLE INGESTION	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☒ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

DSS

APR 22 2013

APR 19 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	MOTHER APR 19 2013	☐ Yes ☒ No ☐ Unk.

Individual Case Safety Report

CaseID: 9410155

9410155-01-00-02

FDA USE ONLY

of 4

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ☐ - ☐ - ☐
Device Code ☐ - ☐ - ☐

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address ***(and Manufacturing Site for Devices)***

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/28/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 RSAE102810EF-003

8. Adverse Event Term(s)
DIFFICULTY BREATHING & RASH

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ☐ - ☐ - ☐ - ☐
Results ☐ - ☐ - ☐ - ☐
Conclusions ☐ - ☐ - ☐ - ☐

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or **11.** ☐ **Corrected Data**

DSS
APR 19 2013 APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report

CaseID: 9410155

INT RECORD

Hyland's®

9410155-01-00-03

COMPLAINT #: RVD102810EF-003

DATE OF COMPLAINT: 10/28/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS (PK OF 4 THROUGH AMAZON)

LOT NO.: THREW AWAY THE BOTTLE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: TOOK ¼ OF THE BOTTLE ON 9/25 AND THEN ON (b) (6) WENT TO ER WITH DIFFICULTY BREATHING. RASH ON HIPS THAT STARTED AROUND THE SAME NIGHT AND IS STILL CONTINUING.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING THE TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/28/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102810EF-003

ADVERSE EVENT SERIOUS: Y / (N)

ADVERSE EVENT REPORTED ON: 10/28/10 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 11/23/10

BY: N/A
QA / QC DIRECTOR

DATE:

DSS
APR 22 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

Individual Case Safety Report

9410155-01-00-04

CaseID: 9410155

ENT DATA FORM

AE #: RAE102810EF-003

COMPLAINT #: RVD102810EF-003

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10/23/10

DSS

APR 22 2013

BY: DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

CaseID: 9412421

9412421-01-00-01

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

or use by user-facilities,
, distributors and manufacturers
for MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (6/10)

Page 1 of 4

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	6 Months or Date of Birth:	☐ Female ☑ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
01/00/2013	06/03/2013

5. Describe Event or Problem

SHE HEARD OF THE RECALL AND WANTED INFORMATION. CHILD HAS HAD 3 DOSES OF BABY TEETHING TABLETS SINCE 3 WEEKS. SINCE 1 1/2 WEEKS MOTHER NOTICED CONSTIPATION, DRY SKIN. SHE THOUGHT IT MAY BE DUE TO INTRODUCTION OF SOLID FOOD (OATMEAL) SINCE 1 MONTH. CHLD HAD THIRD IMMUNICATION ON MAY 10, 2013, AND WAS GIVEN 3 Q 5. MOTHER GAVE LAST DOSE OF BABY TEETHING TABLETS 3 - 4 DAYS AGO. SHE NOTICED IN THE LAST 2 DAYS CHILD AT NIGHT IS "JITTERY", HEAD PULLS AWAY WHILE NURSING, WIDE EYED, LOOK UP AROUND AS THOUGH HE SEES SOMETHING (MOTHER CONSIDERED A GHOST). SHE THOUGHT MAYBE CAFFEINE WAS IN HER MILK ACCIDENTALLY AS HER SON LOOKED LIKE HE WAS ON CAFFEINE. MOTHER IS VERY SENSITIVE TO SOAPS AND HER ALLERGIES. SHE IS SEEING DOCTORY TODAY.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

MOTHER TAKING PRE-NATAL VITAMINS AND .05MG SYNTHROID AT TIME OF INCIDENT.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 2-3 TABS ONCE DAY X 2WKS	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 114193	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

DSS

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

JUN 10 2013

DSS

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: JUN [redacted] 2013 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

JUN 07 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

Individual Case Safety Report

CaseID: 9412421

9412421-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

TUTTI GOULD
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number 310-768-0700
3. Report Source *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)* 05/23/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s) CONSTIPATION, DRY SKIN
9. Manufacturer Report Number 54973 AE # 1386

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)* Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUN 10 2013

DSS
JUN 2013

JUN 07 2013

CaseID: 9412421

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: 2338

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 05/23/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: 114193

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SHE HEARD OF THE RECALL AND WANTED INFORMATION. CHILD HAS HAD 3 DOSES OF BABY TEETHING TABLETS SINCE 3 WEEKS. SINCE 1 ½ WEEKS MOTHER NOTICED CONSTIPATION, DRY SKIN. SHE THOUGHT IT MAY BE DUE TO INTRODUCTION OF SOLID FOOD (OATMEAL) SINCE 1 MONTH. CHILD HAD THIRD IMMUNIZATION ON MAY 10, 2013 AND WAS GIVEN 3 Q 5. MOTHER GAVE LAST DOSE OF BABY TEETHING TABLETS 3 – 4 DAYS AGO. SHE NOTICED IN THE LAST 2 DAYS CHILD AT NIGHT IS "JITTERY, HEAD PULLS AWAY WHILE NURSING, WIDE EYED, LOOK UP AROUND AS THOUGH HE SEES SOMETHING (MOTHER CONSIDERED A GHOST). SHE THOUGHT MAYBE CAFFEINE WAS IN HER MILK ACCIDENTALLY AS HER SON LOOKED LIKE HE WAS ON CAFFEINE. MOTHER IS VERY SENSITIVE TO SOAPS AND HER ALLERGIES. SHE IS SEEING DOCTOR TODAY. CHILD HAS BEEN GIVEN 2 – 3 TABLETS, ONCE A DAY FOR 2 WEEKS. MOTHER TAKING PRENATAL VITAMINS AND .05 MG SYNTHROID AT TIME OF INCIDENT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

RECEIVED
JUN 07 2013

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

CDR

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/23/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD DSS

SECTION III: CORRECTIVE ACTION:

Individual Case Safety Report

9412421-01-00-03

JUN 10 2013

DATE: DSS

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1386 JUN 2013

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/23/13 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: QA / QC DIRECTOR DATE: 06-04-13

JUN 07 2013

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

CaseID: 9412421

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1386 **COMPLAINT #:** 2338

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

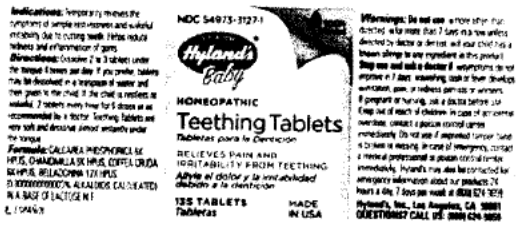
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

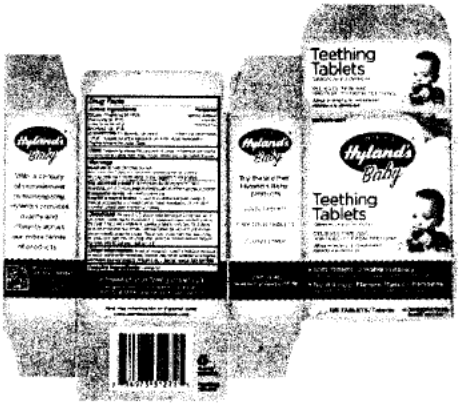
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9412421-01-00-04

SECTION III: **CORRECTIVE ACTION:**

DSS
JUN 10 2013

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
JUN 2013

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: DATE:
QA / QC DIRECTOR

JUN 07 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 9412536

Individual Case Safety Report

9412536-01-00-01

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

ser-facilities,
rs and manufacturers
DRY reporting

of 4

Mfr Report # ~~54973~~

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	7 Months	☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
02/00/2013 - 03/31/2013	05/31/2013

5. Describe Event or Problem

SPOKE WITH MOTHER ON 05/30/2013. IN FEBRUARY AND MARCH OF 2013 CHILD WAS TWITCHING AND JERKING IN EYES AND NECK THAT LOOKED LIKE SPASMS. DOCTOR THOUGHT IT WAS A "LITTLE SEIZURE" BUT DID NOT FEEL NEED TO DO TESTS. SYMPTOMS OCCURRED DURING THE DAY AND INCREASED IN FREQUENCY. SYMPTOMS STOPPED IN MARCH.

6. Relevant Tests/Laboratory Data, Including Dates

DOCTOR DID NOT FEEL NEED TO CONDUCT TESTS

RECEIVED
JUN 07 2013
CDR

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
- #1 HYLAND'S BABY TEETHING TABLETS
- #2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 3 TABS HS ONCE IN WHILE	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 115412	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-3127-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
JUN 10 2013

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

DSS
JUN [redacted] 2013

E. INITIAL REPORTER

1. Name and Address	Phone # (b) (6)
(b) (6)	

USA

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

JUN 07 2013

PLEASE TYPE OR USE BLACK INK

CaseID: 9412536

Individual Case Safety Report

9412536-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number** 310-768-0700
3. **Report Source** *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other: ____
4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 05/24/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)** SEIZURES
9. **Manufacturer Report Number** 54973 AE # 1388

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. **Device Manufacture Date** *(mm/yyyy)*
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Evaluation Codes** *(Refer to coding manual)* Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS
JUN 10 2013

DSS
JUN 07 2013

CaseID: 9412536

Individual Case Safety Report

9412536-01-00-03

PLAINT RECORD

Hyland's

COMPLAINT #: 2340

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/24/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T250

SIZE: 250 TABLETS

LOT NO.: 115412

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CHILD WAS 7 MONTHS OLD AT THE TIME. TAKING AT NIGHT 3 TABLETS AT BEDTIME ONCE IN A WHILE. IN FEBRUARY / MARCH 2013 CHILD WAS TWITCHING AND JERKING IN EYES AND NECK; LOOKS LIKE SPASMS. WENT TO DOCTOR AND DOCTOR THOUGHT IT WAS A "LITTLE SEIZURE", BUT DID NOT FEEL A NEED TO DO TESTS. STOPPED USING PRODUCT IN MARCH 2013 AND REACTIONS STOPPED. REACTIONS WERE DURING THE DAY AND BECOMING MORE FREQUENT. NO FEVER OR ILLNESS AT THE TIME. DOES NOT WANT A REFUND. WANTS TO KNOW WHY BELLADONNA IS IN THE PRODUCT. WANTS BELLADONNA REMOVED FROM PRODUCT. I EXPLAINED THE INGREDIENTS IN PRODUCT TO HER IN DETAIL, EXPLAINED THE HPUS AND THE FACT THAT HOMEOPATHY IS FDA REGULATED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

RECEIVED

JUN 07 2013

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

CDR

INVESTIGATION: REVIEWED BATCH RECORDS. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/24/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

JUN 10 2013

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1388

ADVERSE EVENT SERIOUS: (Y) / N

DSS

JUN 10 2013

ADVERSE EVENT REPORTED ON: 05/24/13 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: QA / QC DIRECTOR DATE: 06-04-13

cc: QA / QC, Packaging, Production, Shipping / Receiving

JUN 07 2013

Form # VD1

Individual Case Safety Report

CaseID: 9412536

9412536-01-00-04

EVENT DATA FORM

AE #: 1388

COMPLAINT #: 2340

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

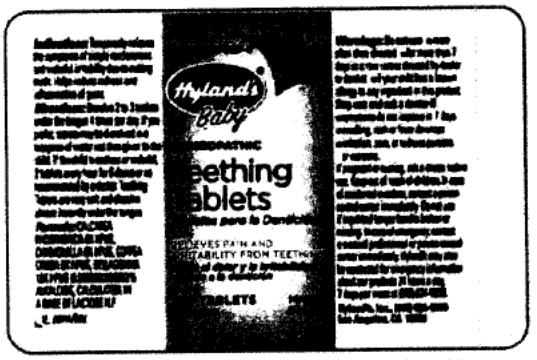
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

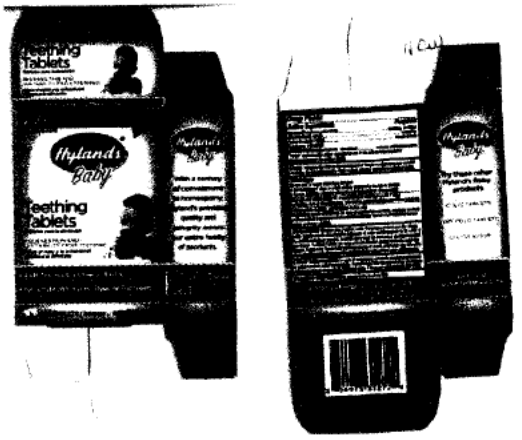
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS
JUN 10 2013

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
JUN 2013

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: DATE: JUN 07 2013
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

9412646-01-00-01

DTC

for use by user facilities, distributors and manufacturers MANDATORY reporting

Dup

CaseID: 9412646

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	4 Months or Date of Birth:	☑ Female ☐ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
05/19/2013	06/03/2013

5. Describe Event or Problem

CHILD SEEMS TO HAVE A FEVER EVERY TIME SHE TAKES TEETHING GEL FOR TH EPAST 6 DAYS. MOTHER STOPPED IT TODAY, 05/25/13. FEVER IS LESS BUT SHE IS PERSPIRING.

HOSPITALIZED FOR 3 DAYS. FEVER GOES FROM 98F TO 104F.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING GEL

#2 TYLENOL

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 SWABS GUM Q 1 - 2 X 1DAY	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 130135A	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-7521-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

USA DSS JUN 19 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

JUN 18 2013

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:

IUTTI GOULD
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 05/25/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #:
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SPIKES FEVER
9. Manufacturer Report Number: 54973 AE # 1387

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUN 19 2013

JUN 18 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

9412646

SECTION I: **COMPLAINT**

COMPLAINT #: 2339

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 05/25/13

PRODUCT: TEETHING GEL

ITEM CODE: TGEL---U0.5Z

SIZE: 0.5 OUNCES

LOT NO.: 130135A

RECEIVED
JUN 17 2013
CDR

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CHILD "RUNS A TEMPERATURE" EACH TIME SHE GIVES IT TO HER FOR THE LAST 6 DAYS. STOPPED GIVING IT TO CHILD. TODAY SHE IS LESS FEVERISH (98°F) BUT IS PERSPIRING. STILL HAS FEVER. LAST DOSE. SHE SETTLES DOWN BUT FEVER SPIKED (101.5°F - 104°F). WENT TO HOSPITAL AND DOCTORS. THEY THINK IT'S EVERY GEL. TAKING TYLENOL FOR FEVER. MOTHER PUTS A LITTLE GEL ON HER FINGER; SWABS ON GUM EVERY 1 – 2 X 1 DAY WHEN IRRITABLE. ADVISED MOTHER TO DISCONTINUE USING PRODUCT AND CONSULT YOUR DOCTOR.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

Individual Case Safety Report

9412646-01-00-03

SECTION II: **INVESTIGATION**

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/25/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1387

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/25/13

BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-04-13

DSS
JUN 19 2013

BY:
QA / QC DIRECTOR

DATE: 06-05-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

JUN 18 2013

CaseID: 9412646

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1387

COMPLAINT #: 2339

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

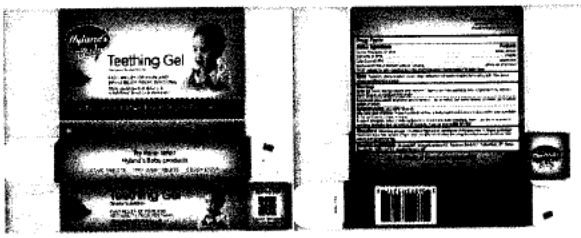
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9412646-01-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
JUN 19 2013

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-04-13

BY: DATE: 06-05-13
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUN 18 2013

Individual Case Safety Report

CaseID: 9412659

9412659-01-00-01

OTC

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	17 Months	☐ Female ☑ Male	26.8 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
05/16/2013	05/24/2013

5. Describe Event or Problem

CHILD EXPERIENCED "JERKING EPISODE" FOR 1 MINUTE, AT THE DAYCARE 1 WEEK AGO, WHICH THE MOTHER INITIALLY DISREGARDED. HE ALSO BROKE OUT IN A RASH. HE SEEMED FINE AFTER. THEN 3 DAYS AGO, HE HAD A SEIZURE AND TREMORS WHILE ASLEEP, WITH A LOW GRADE FEVER OF 100.9. MOTHER TOOK HIM TO THE OUTPATIENT DEPARTMENT AND THEY SCHEDULED HIM FOR A FUTURE EEG AND MRI. YESTERDAY, HE WAS AGAIN GIVEN BABY TEETHING TABLETS AND 1 1/2 HOURS LATER HE BROKE OUT IN A RASH, SAME AS BEFORE. HE ALSO WAS IRRITATED AND HAD DECREASED URINE OUTPUT.

6. Relevant Tests/Laboratory Data, Including Dates

SCHEDULED FOR A FUTURE EEG AND MRI.

RECEIVED
JUN 05 2013
CDR

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD HAS A HISTORY OF ASTHMA AND HAD AN ACUTE EPISODE AT THE END OF APRIL (APPROX. 3 WEEKS AGO). MEDICATIONS: ALBUTEROL, PULMICORT, OMNICEF, ORAPRED, AND UDEROLAL. CHILD ALSO HAD THRUSH AND WAS TAKING NYSTATIN A FEW WEEK AGO.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used

#1 3TABS X 4DOSES X 2 WEEKS

#2

3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*

#1

#2

4. Diagnosis for Use *(Indication)*

#1 RELIEF OF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1 115032

#2

7. Exp. Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS
JUN 06 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Other Healthcare Professional	☐ Yes ☐ No ◉ Unk.

JUN 05 2013

PLEASE TYPE OR USE BLACK INK

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)* Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

TUTTI GOULD
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number** 310-768-0700
3. **Report Source** *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☑ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 05/23/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)** SEIZURE, TREMORS, RASH
9. **Manufacturer Report Number** 54973 AE # 1382

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. **Device Manufacture Date** *(mm/yyyy)*
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Evaluation Codes** *(Refer to coding manual)* Method ___ - ___ - ___ - ___ Results ___ - ___ - ___ - ___ Conclusions ___ - ___ - ___ - ___
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS

JUN 06 2013

JUN 05 2013

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: 2332

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 05/23/13

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET----T250

SIZE: 250 TABLETS

LOT NO.: 115032

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: 17 MONTH OLD CHILD EXPERIENCED "JERKING EPISODE" FOR 1 MINUTE, AT THE DAYCARE 1 WEEK AGO, WHICH THE MOTHER INITIALLY DISREGARDED. HE ALSO BROKE OUT IN A RASH. HE SEEMED FINE AFTER. THEN 3 DAYS AGO, HE HAD A SEIZURE AND TREMORS WHILE ASLEEP, WITH A LOW GRADE FEVER OF 100.9°F. MOTHER TOOK HIM TO THE OUTPATIENT DEPARTMENT AND THEY SCHEDULED HIM FOR A FUTURE EEG AND MRI. YESTERDAY, HE WAS AGAIN GIVEN BABY TEETHING TABLETS AND 1 ½ HOURS LATER HE BROKE OUT IN A RASH, SAME AS BEFORE. HE ALSO WAS IRRITATED AND HAD DECREASED URINE OUTPUT. HE HAS A HISTORY OF ASTHMA AND HAD AN ACUTE EPISODE AT THE END OF APRIL (APPROX. 3 WEEKS AGO). HE WAS ON THE FOLLOWING MEDICATIONS: ALBUTEROL, PULMICORT, OMNICEF, AND ORAPRED. HE ALSO HAD THRUSH AND WAS TAKING NYSTATIN A FEW WEEKS AGO. HIS LAST IMMUNICATIONS WERE ON DEC. 2012. JERKING LASTED 1 MINUTE; SEIZURE WAS DURING SLEEP; RASH – NOT KNOWN. JERKING AND RASH ON 05/16/13; SEIZURE ON 05/20/13; AND RASH ON 05/22/13.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

05/24/13: ALL MEDICINES WERE DISCONTINUED EARLIER IN MAY.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

Individual Case Safety Report

9412659-01-00-04

SECTION II: INVESTIGATION

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. PRODUCT WAS TESTED ACCORDING TO SPECIFICATIONS AND ALL RESULTS WERE WITHIN ACCEPTABLE LIMITS. INSPECTED RETAINED SAMPLES AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 05/22/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1382

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/22/13 BY: EDYTA FRACKIEWICZ

DSS
JUN 06 2013

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 05-30-13

BY:
QA / QC DIRECTOR

DATE: 05-30-13

JUN 05 2013

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

CaseID: 9412659

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1382 COMPLAINT #: 2332

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

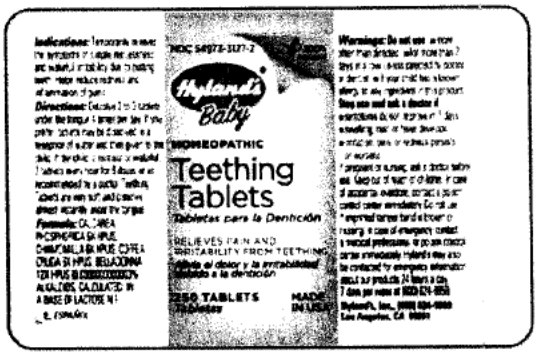
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

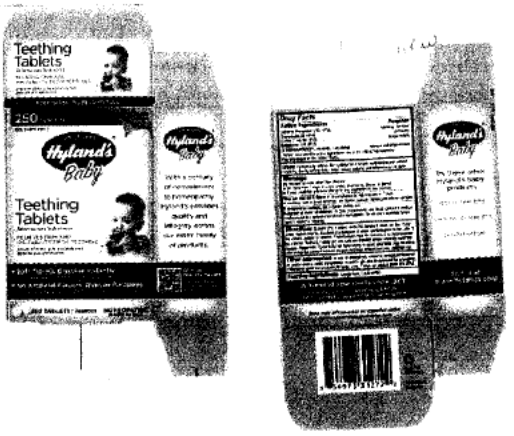
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

Individual Case Safety Report

9412659-01-00-05

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 05-30-13

DSS
JUN 06 2013

BY: QA / QC DIRECTOR DATE: 05-30-13

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUN 05 2013

FORM SAE01

Individual Case Safety Report

9412660-01-00-01

OTC

Dmp

For use by user-facilities, distributors and manufacturers MANDATORY reporting

CaseID: 9412660

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

MEDWATCH

FORM FDA 3500A (6/10)

Page 1 of 4

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	or / Date of Birth:	☑ Female ☐ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
UNKNOWN	05/29/2013

5. Describe Event or Problem

MY DAUGHTER HAS A SEIZURE, AND WE WERE ADMITTED TO (b) (6) FOR A WEEK.

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JUN 05 2013
CDR

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN

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JUN 05 2013
CDR

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNKNOWN

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 UNKNOWN	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	

DSS
JUN 05 2013 JUN 06 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____; Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURE
9. Manufacturer Report Number: 54973 RAE052213EF004

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method ____ - ____ - ____ - ____; Results ____ - ____ - ____ - ____; Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUN 06 2013

JUN 05 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

9412660

SECTION I: **COMPLAINT**

COMPLAINT #: RVD052213EF004

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/24/13

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.:

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #:

E-MAIL: (b) (6)

NATURE OF COMPLAINT: RECEIVED E-MAILED THAT DAUGHTER HAD A SEIZURE AND WAS ADMITTED TO (b) (6) FOR A WEEK.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

3 ATTEMPTS MADE TO REACH CUSTOMER ON 05/22, 05/23, AND 5/24 VIA E-MAIL. CUSTOMER DOES NOT RESPOND.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

CDR

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JUN 05 2013

SECTION III: **CORRECTIVE ACTION:**

Individual Case Safety Report

9412660-01-00-03

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE052213EF004

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/22/13

BY: EDYTA FRACKIEWICZ

DSS

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 05-30-13 JUN 06 2013

BY: N/A

QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

JUN 05 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE052213EF004

COMPLAINT #: RVD052213EF004

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

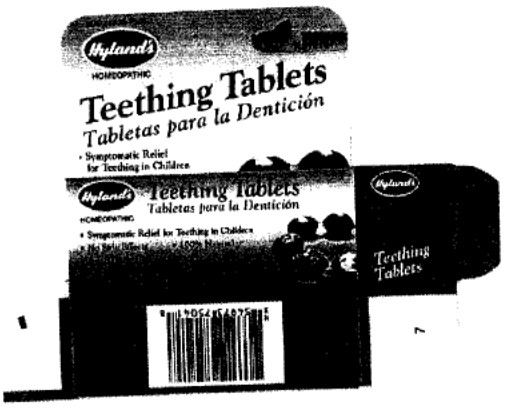
PHONE #:

E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9412660-01-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 05-30-13

DSS
JUN 06 2013

BY: N/A DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUN 05 2013

Individual Case Safety Report

9412682-02-00-01

OTC

NOR

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

CaseID: 9412682

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973 See page 2

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (6/10)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event: 10 Months or Date of Birth:
3. Sex: ☑ Female ☐ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: ____ (mm/dd/yyyy)
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): FEB. 2013 -- MAY 2013

4. Date of This Report (mm/dd/yyyy): 06/14/2013

5. Describe Event or Problem

WHEN CHILD WAS 6 MONTHS OLD, STARTED HAVING SHAKING AND STIFFENING EPISODES WHEN WOULD ZONE OUT FOR 5 - 10 SECONDS. HAPPENED 2 - 3 TIME A WEEK FOR 2 MONTHS. RESOLVED AFTER TEETHING TABLETS WERE DISCONTINUED.

RECEIVED
AUG 20 2013
CDR

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NO KNOWN ALLERGIES.
NO ILLNESSES.
FULL TERM BABY.
NO NEW FOODS AT THE TIME.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2-3TABS Q6 QD X 4 MONTHS
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 A27212/A02813
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

DSS
AUG 20 2013
AUG 21 2013

2. Health Professional? ☐ Yes ☑ No
3. Occupation
4. Initial Reporter Also Sent Report to FDA? ☐ Yes ◉ No ☐ Unk.

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/07/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☑ Follow-up # 1
8. Adverse Event Term(s): POSSIBLE SEIZURES
9. Manufacturer Report Number: 54973 AE # 1405

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360I(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
AUG 21 2013

Individual Case Safety Report

9412682-02-00-03

Case ID 9412682

article #7008 1830 0000 4862 8 5442

STANDARD HOMEOPATHIC

RECEIVED
AUG 20 2013
CDR

June 14, 2013

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $ 9.19 each. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $ 30.26

DSS
AUG 21 2013

Standard Homeopathic Company · Setting the Standard in Homeopathy, Since 1903
210 West 131st Street · Box 61067 · Los Angeles, CA 90061 · (213) 321-4284 · fax (310) 516-8579
P.O. Box 87 · Bryn Mawr, PA 19010 · (215) 520-0580 · fax (215) 520-0582

AUG 20 2013

Case ID: 9412682

9412682-02-00-05

STOMER COMPLAINT RECORD

COMPLAINT #: 2379

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/12/13 (E-MAIL RECEIVED 6/7/13)

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A27213 (1 BOTTLE); A02813 (2 BOTTLES)

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: STARTED USING BABY TEETHING TABLETS WHEN CHILD WAS 4 – 5 MONTHS OLD. USING 2 – 3 TABLETS EVERY 6 HOURS EVERY DAY FOR 4 MONTHS. WHEN CHILD WAS 6 MONTHS, STARTED HAVING SHAKING AND STIFFENING EPISODES, ZONED OUT FOR 5 – 10 SECONDS. HAPPENED 2 – 3 TIME A WEEK FOR 2 MONTHS. STOPPED USING BABY TEETHING TABLETS AT 9 MONTHS (APPROXIMATELY 05/20/13). DOCTOR SAID TO STOP BABY TEETHING TABLETS AND SEE IF SYMPTOMS WENT AWAY AFTER DISCONTINUING PRODUCT. PEDIATRICIAN CALLED THEM EPISODES AND MOTHER CALLED THEM MINI SEIZURES. CUSTOMER WANTS A REFUND FOR 3 BOTTLES OF BABY TEETHING TABLETS. CUSTOMER ON VACATION AND UNABLE TO CALL EARLIER AND DID NOT HAVE BOTTLES AVAILABLE. NO KNOWN ALLERGIES. NO ILLNESSES. FULL-TERM BABY. NO NEW FOODS AT THE TIME.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: BULK LOT # 117628 (A27212), BULK LOT # 117318 (A02813). REVIEWED BATCH RECORDS FOR BOT LOTS. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/12/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

06/14/13: PREPARED REFUND REQUEST TOTALING $ 30.26. 07/26/13: MAILED REFUND CHECK # 509489 TOTALING $ 30.26 ON ARTICLE # 70081830 000486285442.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6) DATE: 06/14/13 & 07/26/13

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1405

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/12/13 BY: EDYTA FRACKIEWICZ

DSS

AUG 21 2013

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 08-06-13

BY: QA / QC DIRECTOR DATE: 08-05-13

cc: QA / QC, Production, Packaging, Shipping / Receiving

AUG 20 2013

FD1

Individual Case Safety Report

Blank

CaseID: 9412689

9412689-02-00-01

OTC

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

MEDWATCH

FORM FDA 3500A (6/10)

Page 1 of 15

Mfr Report # 54973 See page 2

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	4 Months	☐ Female	____ lbs
In confidence	or ____ Date of Birth:	☑ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/03/2013	06/07/2013

5. Describe Event or Problem

USED 1 TABLET ON (b) (6) AND 20 MINUTES LATER CHILD BECAME "LOCKED UP" AND VOMITED. WENT TO HOSPITAL AND DOCTOR DIAGNOSED AS SEIZURE. RELEASED A FEW HOURS LATER AND NO SUBSEQUENT SEIZURES OBSERVED.

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO OTHER MEDICATIONS. NO FAMILY HISTORY OF SEIZURES.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1 TABLET ONCE	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A22713	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone # (b) (6)
(b) (6)	

DSS

AUG 21 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

AUG 20 2013

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # _____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* Patient Code _____ - _____ - _____ Device Code _____ - _____ - _____
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number 310-768-0700
3. Report Source *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)* 06/05/2013
5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☑ Follow-up # 1
8. Adverse Event Term(s) SEIZURES
9. Manufacturer Report Number 54973 AE # 1403

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)* Method _____ - _____ - _____ - _____ Results _____ - _____ - _____ - _____ Conclusions _____ - _____ - _____ - _____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
AUG 21 2013

AUG 20 2013

9412689-02-00-03

Case ID: 9412689 mld
article # 7008
1830 0000 4862
5428

June 7, 2013

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $ 9.19. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $ 9.58

DSS
AUG 21 2013

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210 West 131st Street · Box 61067 · Los Angeles, CA 90061 · (213) 321-4284 · fax (310) 516-8579
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AUG 20 2013

9412689-02-00-05

CaseID: 9412689

STOMER COMPLAINT RECORD

COMPLAINT #: 2375

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/05/13 LEFT MESSAGE

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A22713

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SPOKE WITH CUSTOMER ON 06/06/13. USED 1 TABLETS ON (b) (6) AND 20 MINUTES LATER CHILD BECAME "LOCKED UP", THREW UP. WENT TO HOSPITAL AND DOCTOR DIAGNOSED AS SEIZURE. CHILD RELEASED A FEW HOURS LATER. SAID TO KEEP AN EYE OUT AND DISCONTINUE BABY TEETHING TABLETS. CHILD IS FINE NOW. WANTED A REFUND WHEN OFFERED FOR 1 BOTTLE OF BABY TEETHING TABLETS (135 COUNT). HE FOUND INFORMATION ON TEETHING TABLETS RECALL ON THE INTERNET, WHICH PROMPTED HIM TO CALL. THIS WAS THEIR FIRST TIME USING BABY TEETHING TABLETS. THEY ARE GOING BACK FOR A FOLLOW-UP APPOINTMENT TO DOCTOR. DID NOT KNOW IF HE HAD A FEVER; MAY HAVE. CHILD NOT SICK. NOT PREMATURE. NO OTHER MEDICATIONS. NO FAMILY HISTORY OF SEIZURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

RECEIVED
AUG 20 2013

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

CDR

SECTION II: **INVESTIGATION**

INVESTIGATION: BULK LOT # 118687. REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/05/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

06/07/13: PREPARED REFUND REQUEST TOTALING $ 9.58. 07/26/13: MAILED REFUND CHECK # 509487 TOTALING $ 9.58 ON ARTICLE # 700818300004 86285428.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6) DATE: 06/07/13 & 07/26/13

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1403

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/05/13 BY: EDYTA FRACKIEWICZ

DSS
AUG 21 2013

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 08-06-13

BY: QA / QC DIRECTOR DATE: 08-05-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

AUG 20 2013

Individual Case Safety Report

9412695-02-00-01

NOR

CaseID: 9412695

OTC

or use by user facilities, rters, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973 See page 2

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 15

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 5 Months or Date of Birth:
3. Sex: [x] Female [ ] Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [ ] Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - [ ] Death: ____ *(mm/dd/yyyy)*
   - [ ] Life-threatening
   - [ ] Hospitalization - initial or prolonged
   - [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - [ ] Disability or Permanent Damage
   - [ ] Congenital Anomaly/Birth Defect
   - [x] Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 06/23/2013

4. Date of This Report *(mm/dd/yyyy)*: 06/26/2013

5. Describe Event or Problem

CHILD STARTED SHAKING ON (b) (6) ALSO NOT CONCENTRATING AND HAD A BLANK STARE. HAPPENED TWICE ON THAT DAY. WENT TO THE ER. DOCTOR DIAGNOSED AS SEIZURES AND REFERRED TO A NEUROLOGIST. NO SEIZURES SINCE (b) (6)

6. Relevant Tests/Laboratory Data, Including Dates

BLOOD TESTS WERE NORMAL.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO HISTORY OF SEIZURES IN THE FAMILY.
NO NEW FOODS / FORMULA FED.
HAD A FEVER OF 100.3 SOMETIME ON FRIDAY THAT MOTHER THOUGHT IT WAS FROM TEETHING.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
   #1 HYLAND'S BABY TEETHING GEL
   #2

2. Dose, Frequency & Route Used
   #1 ONE DAB TO GUMS 2-3XDAY
   #2

3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
   #1
   #2

4. Diagnosis for Use *(Indication)*
   #1 TEMP RELIEF OF TEETHING PAIN
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 [ ] Yes [ ] No [ ] Doesn't Apply
   #2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
   #1 130135A
   #2

7. Exp. Date
   #1
   #2

8. Event Reappeared After Reintroduction?
   #1 [ ] Yes [ ] No [ ] Doesn't Apply
   #2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID: 54973-7521-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #
5. Operator of Device: [ ] Health Professional [ ] Lay User/Patient [ ] Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? *(Do not send to FDA)* [ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ *(mm/dd/yyyy)*
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6)
   Phone # (b) (6)

DSS
AUG 21 2013

2. Health Professional? [ ] Yes [x] No
3. Occupation
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [•] No [ ] Unk.

AUG 20 2013

PLEASE TYPE OR USE BLACK INK

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/25/2013

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☑ Follow-up # 1

9. Manufacturer Report Number: 54973 AE#1422

8. Adverse Event Term(s): SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)* Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
AUG 21 2013

AUG 20 2013

9412695-02-00-03

Case ID: 9412695

Article # 70081830004862855 10

STANDARD HOMEOPATHIC

June 26, 2013

(b) (6)

Dear (b) (6)

Pursuant to your letter regarding our Hyland's Baby Teething Gel, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $ 7.59 per bottle. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $8.43

DSS

AUG 20 2013

AUG 21 2013

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210 West 131st Street • P.O. Box 61067 • Los Angeles, CA 90061 • (310) 768-0700 • fax (310) 516-8579

9412695-02-00-05

CUSTOMER COMPLAINT RECORD

CaseID: 9412695

Hyland's

TAKEN BY: EDYTA FRACKIEWICZ

COMPLAINT #: 2407

PRODUCT: BABY TEETHING GEL

DATE OF COMPLAINT: 06/25/13

SIZE: 0.5 OUNCES

ITEM CODE: TGEL----U0.5Z

REPORTER: (b) (6)

LOT NO.: 130135A

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: USING THE PRODUCT 2 – 3 TIMES A DAY FOR 3 – 4 DAYS (JUNE 18 – 22). ON (b) (6) CHILD STARTED SHAKING, NOT CONCENTRATING, BLANK STARE. LASTED ABOUT 20 MINUTES. HAD ABOUT 2 THAT DAY. WENT TO THE ER. HAD BLOOD TESTS – WERE NORMAL. REFERRED TO NEUROLOGIST. DOCTOR DIAGNOSED AS SEIZURES AND RECOMMENDED TO MONITOR. NO SEIZURES SINCE. OFFERED A REFUND AND SHE WANTS IT. TOLD HER NO TO USE BABY TEETHING GEL AND TALK TO THE DOCTOR. NO FAMILY HISTORY OF SEIZURES. NO NEW FOODS / FORMULA FED. FULL TERM BABY. NO HEAD INJURY. HAD A FEVER MOTHER THOUGHT FROM TEETHING (100◦F) SOMETIME ON FRIDAY. MOTHER STATED THAT DOCTOR SAID FEVER WAS OKAY AND DUE TO TEETHING. FEVER BROKE ON FRIDAY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) N

RECEIVED

AUG 20 2013

CDR

PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE) N

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (CIRCLE ONE) N

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/25/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

06/26/13: PREPARED REFUND REQUEST TOTALING $ 8.43. 07/26/13: MAILED REFUND CHECK # 509496 TOTALING $ 8.43 ON ARTICLE # 700818300004 86285510.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6)

DATE: 06/26/2013 & 07/26/13

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1422

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/25/2013

BY: EDYTA FRACKIEWICZ

SECTION V:

DSS

REVIEWED BY MANAGEMENT BY:

DATE: 08-06-13 AUG 21 2013

BY: QA / QC DIRECTOR

DATE: 08-05-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

AUG 20 2013

Form # VD1

Individual Case Safety Report

CaseID: 9424540

9424540-01-00-01

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

...se facilities, ...rs and manufacturers ...reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	8 Months or Date of Birth:	☐ Female ☑ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
11/00/2012	07/02/2013

5. Describe Event or Problem

HAD 3 SEPARATE SEIZURES IN (b) (6) (b) (6) AND (b) (6) WHILE USING HYLAND'S BABY TEETHING TABLETS. SEIZURES WERE ON THE LEFT SIDE OF THE BODY AND CHILD UNRESPONSIVE. HOSPITALIZED AFTER TWITCHING, JERKING, FOAMING AT MOUTH, AND TURNED BLUE ON THIRD SEIZURE.

6. Relevant Tests/Laboratory Data, Including Dates

NEUROLOGICAL TESTS WERE NORMAL.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO OTHER MEDICATIONS. NOT PRE-MATURE. NO HISTORY OF HEAD INJURY. NO FAMILY HISTORY OF SEIZURES. BOTTLE FED. HAD A FEVER DURING THE FIRST SEIZURE (100.1 - 101F); NO FEVER DURING THE OTHER SEIZURES.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 AS NEEDED FOR 3 MONTHS	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 114465	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

DSS JUL 26 2013

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

USA

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

JUL 25 2013

Individual Case Safety Report

CaseID: 9424540

9424540-01-00-02

of 5

FDA USE ONLY

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address ***(and Manufacturing Site for Devices)***

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number

310-768-0700

3. Report Source *(Check all that apply)*

☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*

07/01/2013

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*

☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number

54973 AE # 1430

8. Adverse Event Term(s)

SEIZURES, HOSPITALIZATION

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*

Method ____ - ____ - ____ - ____

Results ____ - ____ - ____ - ____

Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or **11.** ☐ **Corrected Data**

DSS

JUL 26 2013

JUL 25 2013

Individual Case Safety Report

9424540-01-00-03

COMPLAINT RECORD

C 9424540

Hyland's

COMPLAINT #: 2421

DATE OF COMPLAINT: 07/01/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: 114465

REPORTER: (b) (6)

ADDRESS:

RECEIVED

CITY:

STATE: (b) (6)

JUL 25 2013

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

CDR

E-MAIL:

NATURE OF COMPLAINT: STARTED TEETHING 8 MONTHS AGO AND PURCHASED TABLETS AT WAL-MART. STARTED GIVING TABLETS AND 3 DAYS LATER IN (b) (6) HAD A SEIZURE DESCRIBED AS BECOMING UNRESPONSIVE, TWITCHING, JERKING LEFT HALF OF BODY. AMBULANCE PICKED HIM UP AND WENT TO (b) (6) AND TESTING SHOWED NOTHING. SAID IT WAS ODD THAT ONLY HALF HIS BODY SEIZED. STAYED IN HOSPITAL / ER FOR 6 HOURS. THEY CONTINUED USING TEETHING TABLETS. SECOND SEIZURE HAPPENED END OF (b) (6) ONLY LEFT SIDED. HAD A THIRD SEIZURE IN (b) (6) GOT A TABLET BEFORE BED THAT DAY PRIOR TO SEIZURE. DID NOT GIVE ANY TEETHING TABLETS AFTER THAT. THIRD SEIZURE WORSE BECAUSE HE STOPPED BREATHING, TURNED BLUE, FOAM OUT OF MOUTH, TWITCHING ON ONE SIDE. WENT TO ER AND STAYED OVERNIGHT. DOCTORS NOT SURE OF THE CAUSE. HAS BEEN TO NEUROLOGIST AND ALL TESTS ARE NORMAL. STOPPED BABY TEETHING TABLETS IN (b) (6) AFTER THIRD SEIZURE AND HAS HAD NO OTHER SEIZURES. HAS HAD MEDICAL EXPENSES AND WANTS A SETTLEMENT. OFFERED A REFUND FOR THE BOTTLE BUT DECLINED. GAVE HIM OUR MAILING ADDRESS BECAUSE HE WANTED TO KNOW HOW HE COULD CONTACT OUR LEGAL DEPARTMENT. HE HAD MEDICAL INSURANCE BUT HAS EXPENSES RELATED TO CO-PAYS AND TRAVEL AS A RESULT OF CHILD'S SEIZURES.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

NO OTHER MEDICATIONS. NOT PRE-MATURE. NO HISTORY OF HEAD INJURY. NO FAMILY HISTORY OF SEIZURES. BOTTLE FED. HAD A FEVER DURING THE FIRST SEIZURE 100.1 – 101: NO FEVER DURING THE OTHER SEIZURES.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 07/01/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1430

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 07/01/13 BY: EDYTA FRACKIEWICZ

DSS

JUL 26 2013

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 07-11-13

BY:

QA / QC DIRECTOR

DATE: 07-10-13

cc: QA / QC, Packaging, Production, Shipping / Receiving

JUL 25 2013

Form # VD1

9424540-01-00-04

ISA SINCE 1903

Serious Adverse Event
SAE-0029-2013

Product in Inventory:

No units of Hyland's Baby Teething Tablet (BTET), lot #114465, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (b) (4) units, has been distributed.

Review of Records:

The BTET lot #114465 was manufactured using (b) (4) lot # (b) (4) The associated manufacturing and packaging records were reviewed and did not reveal any issues.

Atropine and Scopolamine testing was conducted on the final container product BTET # 114465, and it was within specification, with results ≤ (b) (4) ppm.

The final product lot #114465 was submitted for microbiological testing to (b) (4) on 01/12/2012 and the results met the criteria for acceptance for Microbial Limits Test for Aerobic Plate Count, Yeast and Mold Count, *Escherichia cola, Salmonella sp., Pseudomonas aeruginosa, Staphylococcus aureus and Clostridia sp.*

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the product. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specification of: color – white, odor – none and taste – faintly sweet.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation System was conducted and no issues were reported for this lot or the associated intermediate powder.

Of the (b) (4) units manufactured a total of 2 complaints, including this one, have been received on Hyland's Baby Teething Tablet (BTET), lot #114465.

A review of the Customer Complaint system did reveal that on 5/25/2012 a report of "tablets are crumbly and lots of powder in the bottle" was reported for this same BTET lot #114465. That complaint was investigated under Complaint # 1487. The incident was investigated and no issues with the manufacturing or packaging process that could have contributed to that incident was identified.

The two incidents are not considered related.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for this lot of Hyland's Baby Teething Tablet (BTET), lot #114465. Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

07/10/13
Date

DSS
JUL 26 2013

JUL 25 2013

Individual Case Safety Report

9424540-01-00-05

CaseID: 9424540

Hyland's

E EVENT DATA FORM

AE #: 1430 COMPLAINT #: 2421

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

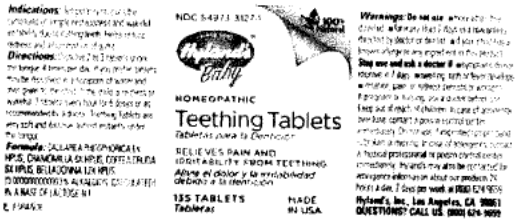
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

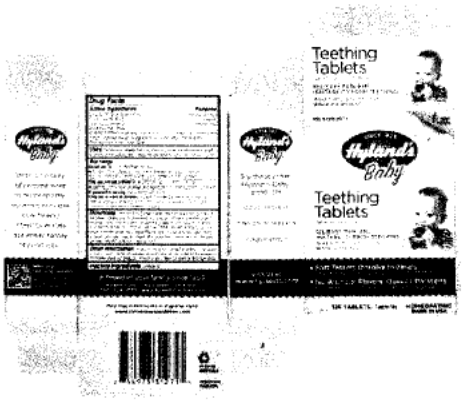
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 07-11-13

BY: QA / QC DIRECTOR DATE: 07-10-13

DSS JUL 26 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUL 25 2013

Individual Case Safety Report

CaseID: 9461703

9461703-01-00-01

nsumer Report OTC

UNTARY reporting
nts, product problems and
roduct use errors

Page ~~1 of 2~~ 1/1 CDER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 520690

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) in confidence	1.5 Months (b) (6)	☐ Female ☑ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ **Adverse Event** ☑ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/24/2013	08/14/2013

5. **Describe Event, Problem or Product Use Error**

My son born (b) (6) was taking Hylands teething tablets since he was a month in a half old. So since (b) (6) to (b) (6) He was hospitalized numerous times for Unknown reasons of high fever, constipation, agitation, respiratory problems, skin problems, emergency sinus surgery. He is now having delayed speech,vision problems, urination problems and respiratory as well. There were many times when the only medication he was taking were the teething tablets.

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
Race:White Medical Conditions: Allergies: Important Information: RX Meds: OTC Meds: gummie vitamins

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*

#1 Name: Hylands teething tablets
Strength:
Manufacturer: Hylands

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 as needed	--	--
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 04/28/2010 - 12/31/2013
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 Teething
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name** CTU
2. **Common Device Name** AUG 15 2013
3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
(b) (6)

DSS
AUG 15 2013

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Case Safety Report

9471241-01-00-01

CaseID: 9471241

OTC

For use by user-facilities, ers, distributors and manufacturers .or MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statem ent on reverse.

MEDWATCH

FORM FDA 3500A (6/10)

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	9 Months	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
'04/00/2010 TO PRESENT	08/01/2013

5. Describe Event or Problem

SPRING OF 2010 CHILD BEGAN EXPERIENCING NON-CONVULSANT SEIZURES WITH SYMPTOMS OF BLUE LIPS, FINGERS, AND TOES, EYES BLANK AND DILATED, MOUTH HUNG OPEN AND DROOLING, SHALLOW BREATHING. SEIZURES OCCURRED EVERY OTHER WEEK UNTIL HE WAS 15 MONTHS OF AGE AND THEN STOPPED AND WERE FOLLOWED BY SEVERAL LONGER SEIZURE EPISODES. CHILD HAS DIFFICULTY REACHING MILESTONES AND IS DIAGNOSED WITH AUTISM DISORDER.

6. Relevant Tests/Laboratory Data, Including Dates

EKG, EEG, MRI WITH NORMAL RESULTS.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD HAS ALSO UNDERGONE DEVELOPMENTAL TESTING BECAUSE OF DIFFICULTY REACHING MILESTONES.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 UNKNOWN	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

DSS

AUG 19 2013

2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

Individual Case Safety Report

CaseID: 9471241

9471241-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # _____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*
Patient Code - - Device Code - -
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☑ Other:
LAWYER

4. Date Received by Manufacturer *(mm/dd/yyyy)*
07/25/203

5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 AE #1484

8. Adverse Event Term(s)
NON-CONVULSANT SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: _____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*
Method - - - Results - - - Conclusions - - -
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: _____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

AUG 16 2013 AUG 19 2013

CaseID: 9471241

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's®

SECTION I: **COMPLAINT**

COMPLAINT #: 2490

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 07/25/13

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET----T125

SIZE: 125 TABLETS

LOT NO.: NOT AVAILABLE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SPRING OF 2010 CHILD BEGAN EXPERIENCING NON-CONVULSANT SEIZURES WITH SYMPTOMS OF BLUE LIPS, FINGERS, AND TOES, EYES BLANK AND DILATED, MOUTH HUNG OPEN AND DROOLING, SHALLOW BREATHING. SEIZURES OCCURRED EVERY OTHER WEEK UNTIL HE WAS 15 MONTHS OF AGE AND THEN STOPPED AND WERE FOLLOWED BY SEVERAL LONGER SEIZURE EPISODES. CHILD HAS DIFFICULTY REACHING MILESTONES AND IS DIAGNOSED WITH AUTISM DISORDER. CHILD WAS BORN FULL TERM FROM UNCOMPLICATED VAGINAL DELIVERY. CHILD RECEIVED TREATMENT AT THE NEUROLOGY CLINIC AT (b) (6) HOSPITAL IN (b) (6). CHILD HAS HAD AN EKG, EEG, AND MRI. HAS ALSO UNDERGONE DEVELOPMENTAL TESTING BECAUSE OF DIFFICULTY REACHING MILESTONES. ALSO SEEN AT (b) (6) HOSPITAL NEUROLOGY AND (b) (6) MEDICAL CENTER. RESULTS OF EKG, EEG, AND MRI WERE NORMAL. THERE WAS NO PRENATAL EXPOSURE TO CIGARETTES, ALCOHOL, OR TOXIC SUBSTANCES.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

RECEIVED
AUG 16 2013
CDR

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 07/25/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

Individual Case Safety Report

9471241-01-00-03

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1484

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 07/25/13

BY: EDYTA FRACKIEWICZ

DSS
AUG 19 2013

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 08-06-13

BY:
QA / QC DIRECTOR

DATE: 08-05-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

AUG 16 2013

Form # VD1

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE 117

Product in Inventory:

The reporter was only able to provide the product name, Hyland's Baby Teething Tablets, no the lot number for the units involved and no confirmation if it was a Hyland's product.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

08/02/13
Date

Individual Case Safety Report

9471241-01-00-04

DSS
AUG 19 2013

AUG 16 2013

CaseID: 9471241

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1484 COMPLAINT #: 2490

SECTION I: **PATIENT INFORMATION** *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9471241-01-00-05

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 08-06-13

BY: QA / QC DIRECTOR DATE: 08-05-13

DSS
AUG 19 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

AUG 16 2013

Individual Case Safety Report

CaseID: 9486434

9486434-01-00-01

Consumer Report

OLUNTARY reporting of vents, product problems and product use errors

The FDA Safety Information and Adverse Event Reporting Program

Page ~~1 of 2~~ 1/1

CDER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 522124

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	8 Months (b) (6)	☑ Female ☐ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)*
☑ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/18/2013	08/26/2013

5. Describe Event, Problem or Product Use Error

My daughter started teething around 4 months. A family member recommended Hyland's Teething Tablet about a month later and I started giving them to her. In (b) (6) (b) (6) she had her first seizure.I took her to the ER and eventually ended up at the neurologist. They ran an EEG and then an MRI and both came back normal. I heard from a friend that there was a recall.

6. Relevant Tests/Laboratory Data, Including Dates

EEG and MRI both came back normal

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:Other Medical Conditions: None Allergies: None Important Information: None RX Meds: None OTC Meds: None

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Name: hyland teething tablet
Strength:
Manufacturer:

OTC

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 03/01/2013 - 07/01/2013
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: CTU

2. Common Device Name

AUG 27 2013

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: (b) (6)
Address:
City: State: -- ZIP:

DSS
AUG 27 2013

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

(1)

Individual Case Safety Report

9570361-01-00-01

9/18/13 Case ID: 9570361 #

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

se by user-facilities,
ributors and manufacturers
JDATORY reporting

MFR Report # PG 2 [illegible]4973 7008 1823 0000
UF/Importer Report # 8628 5770

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	6 Months or Date of Birth:	☑ Female ☐ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
09/08/2013	09/10/2013

5. Describe Event or Problem

(b) (6) HER DAUGHTER WOKE UP SCREAMING, SHE GAVE HER 1 TABLET OF BABY TEETHING TABLETS, THEN SHE FELL ASLEEP. 20 MINUTES LATER WHEN SHE WOKE UP SCREAMING, SHE PICKED HER UP AND SHE HAD A SEIZURE. HER EYES ROLLED BACK INTO HER HEAD, SHE WAS STIFF AND BARELY BREATHING. CHILD COULD NOT MOVE HER ARMS OR LEGS AFTER THE SEIZURE, BUT REGAINED HER LEG MOVEMENT BY THE TIME THEY REACHED THE HOSPITAL, AND 1.5 HOURS LATER HER ARM MOVEMENT RETURNED.

RECEIVED
SEP 26 2012
CDR

6. Relevant Tests/Laboratory Data, Including Dates

BLOOD AND URINE TESTS. BLOOD TEST RESULTS NORMAL; URINE TEST RESULTS PENDING.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

HISTORY OF A MILD SEIZURE 1 MONTH AGO (SHAKING AND JERKING LASTING ONE MINUTE)

AT HOSPITAL, CHILD GIVEN TYLENOL FOR THE RESIDUAL MUSCLE PAIN AND STIFFNESS.

IMMUNIZATION SHOTS RECEIVED ON AUGUST 20TH.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 1 TABLET ONCE / 2 MONTHS	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF OF TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A40313/A79913	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
SEP 27 2013

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address — Phone # (b) (6)

(b) (6)

ISA
SEP 26 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ◉ Unk.

Individual Case Safety Report

CaseID: 9570361

9570361-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy):
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy):
9. Approximate Age of Device:
10. Event Problem Codes (Refer to coding manual): Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

TUTTI GOULD
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply): ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 09/08/2013

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #:

7. Type of Report (Check all that apply): ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURE

9. Manufacturer Report Number: 54973 AE # 1506

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____
4. Device Manufacture Date (mm/yyyy):
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes (Refer to coding manual): Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
SEP 27 2013

SEP 26 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Ca[illegible]9570361

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: 2515

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 09/08/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABLETS

LOT NO.: A40313 A79913

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: MOTHER SAID SHE CALLED YESTERDAY TO INQUIRE ABOUT THE TEETHING TABLETS. (b) (6) SHE WAS IN THE HOSPITAL FOR 6 HOURS WITH HER DAUGHTER FOR A SEIZURE THAT LASTED 5 MINUTES, STARTING AT 7 AM. (b) (6) HER DAUGHTER WOKE UP SCREAMING, SHE GAVE HER 1 TABLET OF BABY TEETHING TABLETS, THEN SHE FELL ASLEEP. 20 MINUTES LATER WHEN SHE WOKE UP SCREAMING, SHE PICKED HER UP AND SHE HAD A SEIZURE. HER EYES ROLLED BACK INTO HER HEAD SHE WAS STIFF AND BARELY BREATHING. CHILD COULD NOT MOVE HER ARMS OR LEGS AFTER THE SEIZURE, BUT REGAINED HER LEG MOVEMENT BY THE TIME THEY REACHED THE HOSPITAL, AND 1.5 HOURS LATER HER ARM MOVEMENT RETURNED. SHE HAS BEEN GIVING HER DAUGHTER BABY TEETHING TABLETS FOR THE PAST 2 MONTHS (MIXED CONTENTS OF REMAINING TABLETS OF ONE BOTTLE INTO SECOND BOTTLE). SHE ESTIMATES SHE HAD GIVEN 20 TABLETS IN THE PAST 2 MONTHS AS NEEDED. MOTHER SAID SHE HAD ALSO BEEN GIVING TYLENOL. THE DOCTORS SAID "THEY DON'T KNOW WHAT IT IS". MOTHER MENTIONED THAT A MONTH AGO, HER DAUGHTER HAD A BRIEF EPISODE OF JERKING AND SHAKING LASTING ONE MINUTE. AUGUST 20, 19 DAYS AGO SHE RECEIVED HER IMMUNIZATION "SHOTS". BLOOD AND URINE TESTS CONDUCTED ON 09/08/13. BLOOD TESTS NORMAL; URINE TEST RESULTS PENDING.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9570361-01-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/08/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

DSS
SEP 27 2013

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1506

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/08/13

BY: TUTTI GOULD

SEP 26 2013

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 09-17-13

BY: QA / QC DIRECTOR

DATE: 09-16-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

9570381-01-00-04

1NDARD
OPATHIC
E USA SINCE 1903

Serious Adverse Event
SAE-0041-2013

The customer provided two (2) lot numbers that were associated with this complaint for Hyland's Baby Teething Tablets. The lot numbers were A79913 and A40313; however lot number A40313 is associated with Hyland's Baby Cold Tablets and not Baby Teething Tablets. A review of both batches was conducted.

Product in Inventory:

No units of Hyland's Hyland's Baby Teething Tablets (BTET), lot #A79913, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (b) (4) units, has been distributed.

No units of Hyland's Hyland's Baby Cold Tablets (BCLD), lot #A40313, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (b) (4) units, has been distributed.

Review of Records:

The BTET lot # A79913 was manufactured using bulk lot # 120264 and BCLD lot # A40313 was manufactured using bulk lot # 119279. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

BTET lot # A79913 and BCLD lot # A40313 were inspected against the Commercial Specifications and all results met the specification. Both lots were submitted for Microbial testing and the results were within specification.

The BTET lot # A79913, bulk lot # 120264 was tested for Total Atropine and Scopolamine levels and was found to meet the specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specification of: color – white, odor – none and taste – faintly sweet.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation System was conducted and no investigations were associated with these lots.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets (BTET), lot # A799143, or Hyland's Baby Cold Tablets, lot # A40313.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets (BTET), lot # A799143, or Hyland's Baby Cold Tablets, lot # A40313. Manufacture and processing occurred within established procedures to ensure product quality.

DSS
SEP 27 2013

Prepared by

09/13/2013
Date

SEP 26 2013

CC-0570-2013
AE-0354-2013
SAE #123

Individual Case Safety Report

CaseID: 9570361

9570361-01-00-05

E EVENT DATA FORM

AE #: 1506 COMPLAINT #: 2515

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
SEP 27 2013

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 09-17-13

BY: QA / QC DIRECTOR DATE: 09-16-13

SEP 26 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

CaseID: 9570446

9570446-01-00-01

Form Approved: OMB No. 09 10-029 1, Ex pires 12/31/11
See OMB statement on reverse.

: by user-facilities,
ibutors and manufacturers
DATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 7 Months or Date of Birth:
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - ☐ Death: ____ *(mm/dd/yyyy)*
   - ☐ Disability or Permanent Damage
   - ☐ Life-threatening
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Hospitalization - initial or prolonged
   - ☑ Other Serious (Important Medical Events)
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*: 09/00/2013

4. Date of This Report *(mm/dd/yyyy)*: 09/05/2013

5. Describe Event or Problem

CHILD SUFFERED MILD SEIZURES PAST WEEK AFTER TAKING BABY TEETHING TABLETS. HAD 5 MINI SEIZURES IN 10 MINUTES.

RECEIVED
SEP 26 2012
CDR

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNKNOWN

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
   - #1 HYLAND'S BABY TEETHING TABLETS
   - #2

2. Dose, Frequency & Route Used
   - #1 UNKNOWN DOSAGE
   - #2

3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
   - #1
   - #2

4. Diagnosis for Use *(Indication)*
   - #1 TEMP RELIEF TEETHING PAIN
   - #2

5. Event Abated After Use Stopped or Dose Reduced?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
   - #1
   - #2

7. Exp. Date
   - #1
   - #2

8. Event Reappeared After Reintroduction?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
SEP 27 2013

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6) USA
   Phone #

SEP 26 2013

2. Health Professional? ☐ Yes ☑ No
3. Occupation: NA
4. Initial Reporter Also Sent Report to FDA: ☐ Yes ☐ No ◉ Unk.

Individual Case Safety Report

CaseID: 9570446

9570446-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ___ - ___ - ___; Device Code ___ - ___ - ___
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 09/04/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURES
9. Manufacturer Report Number: 54973 AE # 1505

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method ___ - ___ - ___ - ___; Results ___ - ___ - ___ - ___; Conclusions ___ - ___ - ___ - ___
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
SEP 27 2013

SEP 26 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

9570446

SECTION I: COMPLAINT

COMPLAINT #: 2514

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 09/04/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: NOT PROVIDED

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #:

E-MAIL:

NATURE OF COMPLAINT: PER INTERNET POST: 7 MONTH GRANDSON SUFFERED MILD SEIZURES PAST WEEK AFTER TAKING TABLETS. HAD 5 MINI ONES IN 10 MINUTES. NO CONTACT INFORMATION PROVIDED FOR THIS CUSTOMER.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9570446-01-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 09/04/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS
SEP 27 2013

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1505

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/04/13

BY: EDYTA FRACKIEWICZ

SECTION V:

SEP 26 2013

REVIEWED BY MANAGEMENT BY: R Watt

DATE: 09-19-13

BY: Dyman Parker
QA / QC DIRECTOR

DATE: 09-17-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

9570446-01-00-04

STANDARD HOMEOPATHIC
THE USA SINCE 1903

Serious Adverse Event
SAE 122

Product in Inventory:

The reporter was only able to provide the product name, Hyland's Baby Teething Tablets, not the lot number for the unit involved

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

09/05/13
Date

DSS
SEP 27 2013

SEP 26 2013

AE # 1505
Complaint # 2514
CC-0556-2013
AE-0344-2013
SAE-0040-2013

Individual Case Safety Report

CaseID: 9570446

9570446-01-00-05

RSE EVENT DATA FORM

AE #: 1505 COMPLAINT #: 2514

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE:

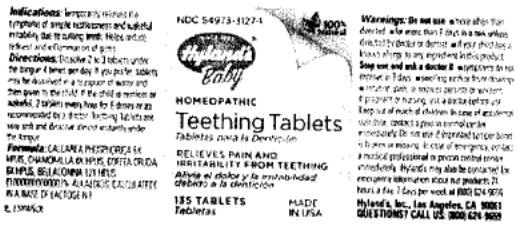
COUNTRY: USA ZIP CODE:

PHONE #:

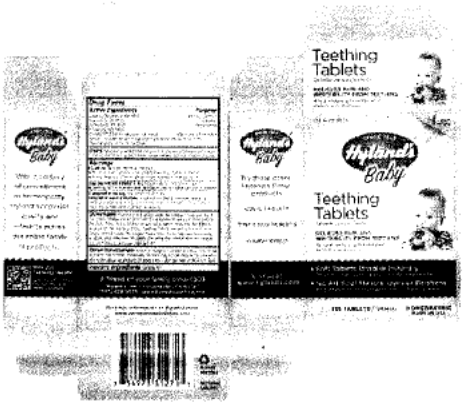
E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: CORRECTIVE ACTION:

DSS
SEP 27 2013

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SEP 26 2013

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 09-19-13

BY: QA / QC DIRECTOR DATE: 09-17-13

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

9622302-01-00-01

y ser-facilities,
itors and manufacturers
ATORY reporting

Page 1 of 5

Form Approved: OMB No. 0910-0291 Expires: 12/31/11
See OMB statement on reverse.

CaseID 9622302

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	31 Years	☑ Female	lbs
In confidence	or Date of Birth:	☐ Male	or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
09/19/2013	09/23/2013

5. Describe Event or Problem

MOTHER APPLIED HYLAND'S TEETHING GEL TO HER OWN GUMS TO SEE WHAT WOULD HAPPEN. SHE GOT HIVES, ITCHING ALL OVER BODY, AND HER THROAT SWELLED. TOOK A BENADRYL AND THE SYMPTOMS RESOLVED. DID NOT HAVE DIFFICULTY BREATHING. WAS WORRIED ABOUT HER THROAT AND SHE WENT TO THE EMERGENCY ROOM. SHE WAS RELEASED FROM ER AND NOT ADMITTED.

RECEIVED
OCT 10 2013

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN. ER TOOK A "WAIT AND SEE" APPROACH.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

HAS THIS TYPE OF ALLERGIC REACTION WHEN SHE EATS MANGOS.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING GEL

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 ONE APPLICATION TO GUMS	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 119022	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-7521-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: OCT 11 2013 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

OCT 10 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ◉ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 9622302

9622302-01-00-02

FDA USE ONLY

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
09/23/2013

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
ALLERGIC REACTION

9. Manufacturer Report Number
54973 AE # 1510

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
OCT 11 2013

OCT 10 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report

9622302-01-00-03

PLAINT RECORD

Hyland's 9622302

COMPLAINT #: 2519

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 09/20/13

PRODUCT: HYLAND'S TEETHING GEL

ITEM CODE: TGEL----U0.5Z

SIZE: 0.5 OZ.

LOT NO.: 119022

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: MOTHER APPLIED TEETHING GEL TO HER OWN GUMS TO SEE WHAT WOULD HAPPEN. SHE GOT HIVES, ITCHING ALL OVER BODY, AND HER THROAT SWELLED. HAS ONLY HAD THIS TYPE OF REACTION WITH MANGOS BECAUSE SHE IS ALLERGIC TO THEM. TOOK A BENADRYL AND THE SYMPTOMS RESOLVED. DID NOT HAVE DIFFICULTY BREATHING. WAS WORRIED ABOUT HER THROAT AND SHE WENT TO THE EMERGENCY ROOM. SHE HAD TAKEN BENADRYL SO THEY TOOK A "WAIT AND SEE" APPROACH IN THE ER. SHE WAS RELEASED FROM ER AND NOT ADMITTED. DIAGNOSED IN ER AS "ALLERGIC REACTION".

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 09/23/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS
OCT 11 2013

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1510

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/23/13

BY: EDYTA FRACKIEWICZ

OCT 10 2013

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt

DATE: 10-01-13

BY: Eric Baum
QA / QC DIRECTOR

DATE: 10-01-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0045-2013

Product in Inventory:

No units of Hyland's Baby Teething Gel (TGEL), lot #119022, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (b) (4) units, has been distributed.

Review of Records:

The TGEL lot # 119022 was manufactured using bulk lot # 118923. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Certificate of Analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Gel lot # 119022. In addition it was tested for Total Atropine and Scopolamine levels and was found to meet the specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Gel lot # 119022.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Gel lot # 119022.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

10/1/13
Date

DSS
OCT 11 2013

Individual Case Safety Report

9622302-01-00-04

OCT 10 2013

CC-0621-2013
AE-0373-2013
SAE #127
AE #1510
Complaint #2519

Individual Case Safety Report

CaseID: 9622302

9622302-01-00-05

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1510

COMPLAINT #: 2519

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

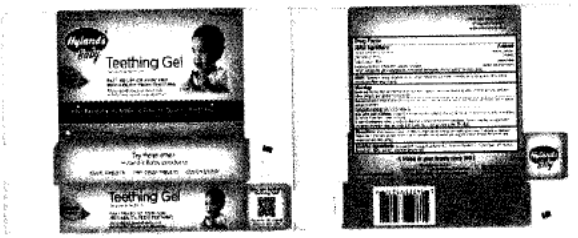
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS
OCT 11 2013

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-01-13 OCT 10 2013

BY: QA / QC DIRECTOR DATE: 10-01-13

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 9627012

9627012-01-00-01

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

er-facilities,
s and manufacturers
)RY reporting

Mfr Report # 2280705-2013-00059

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (1/09)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	2 Years	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☑ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
08/05/2011	10/09/13

5. **Describe Event or Problem**

Approximately 30 minutes after the child was administered Baby Orajel™ he became "white as a ghost" with blue fingernails and lips. He was admitted to the hospital and diagnosed with methemoglobinemia.

RECEIVED
OCT 11 2013
CDR

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*

#1 Baby Orajel™ Oral Pain Reliever for Teething OTC

#2 (continued) Benzocaine 7.5%

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 unk dose, 1X, oral	#1 08/05/2011
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 To alleviate oral pain	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 LL0124	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC# or Unique ID**: 10237-735-42

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Clindamycin, Tylenol #3, Motrin since 08/03/2011.

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?** ☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

DSS

10. **Device Available for Evaluation?** *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)* OCT 15 2013

11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

E. INITIAL REPORTER

1. **Name and Address** — **Phone #** (b) (6)

(b) (6)

OCT 11 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ◉ Unk.

Individual Case Safety Report

CaseID: 9627012

9627012-01-00-02

11

FDA USE ONLY

1. Check One	2. UF/Importer Report Number
☐ User Facility ☐ Importer	

3. User Facility or Importer Name/Address

4. Contact Person	5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)	7. Type of Report	8. Date of This Report (mm/dd/yyyy)
	☐ Initial ☐ Follow-up # ____	

9. Approximate Age of Device	10. Event Problem Codes (Refer to coding manual)
	Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____

11. Report Sent to FDA?	12. Location Where Event Occurred
☐ Yes ____ (mm/dd/yyyy) ☐ No	☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer?	
☐ Yes ____ (mm/dd/yyyy) ☐ No	

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address ***(and Manufacturing Site for Devices)***

Jill D. Ferentz
Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543

2. Phone Number

609-806-1428

3. Report Source *(Check all that apply)*

☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☑ Other: Attorney

4. Date Received by Manufacturer *(mm/dd/yyyy)*

02/07/2012

5.

(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*

☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number

2280705-2013-00059

8. Adverse Event Term(s)

Methemoglobinemia

. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event	2. If Follow-up, What Type?
☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____	☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer?	**4. Device Manufacture Date** *(mm/yyyy)*
☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____	**5. Labeled for Single Use?** ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*

Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type	8. Usage of Device
☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____	☐ Initial Use of Device ☐ Reuse ☐ Unknown **9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**

10. ☑ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

Baby Orajel® oral pain reliever for teething labels are attached.

Hospital Report is attached.

This report was escalated through litigation without first coming through consumer relations, therefore, the event was not reported within the required 15 day period for serious adverse events of this nature. This gap has since been closed with a procedure to review SAERS that come in through litigation in consumer relations and ensure that reports are forwarded to FDA within the required 15 days after date of awareness.

This report and the information submitted under this report do not constitute an admission that the drug or Church & Dwight Co., Inc. or any of its employees caused or contributed to the event described herein or that the event as reported to Church & Dwight actually occurred.

DSS
OCT 15 2013

OCT 11 2013

9627012-01-00-03

DSS
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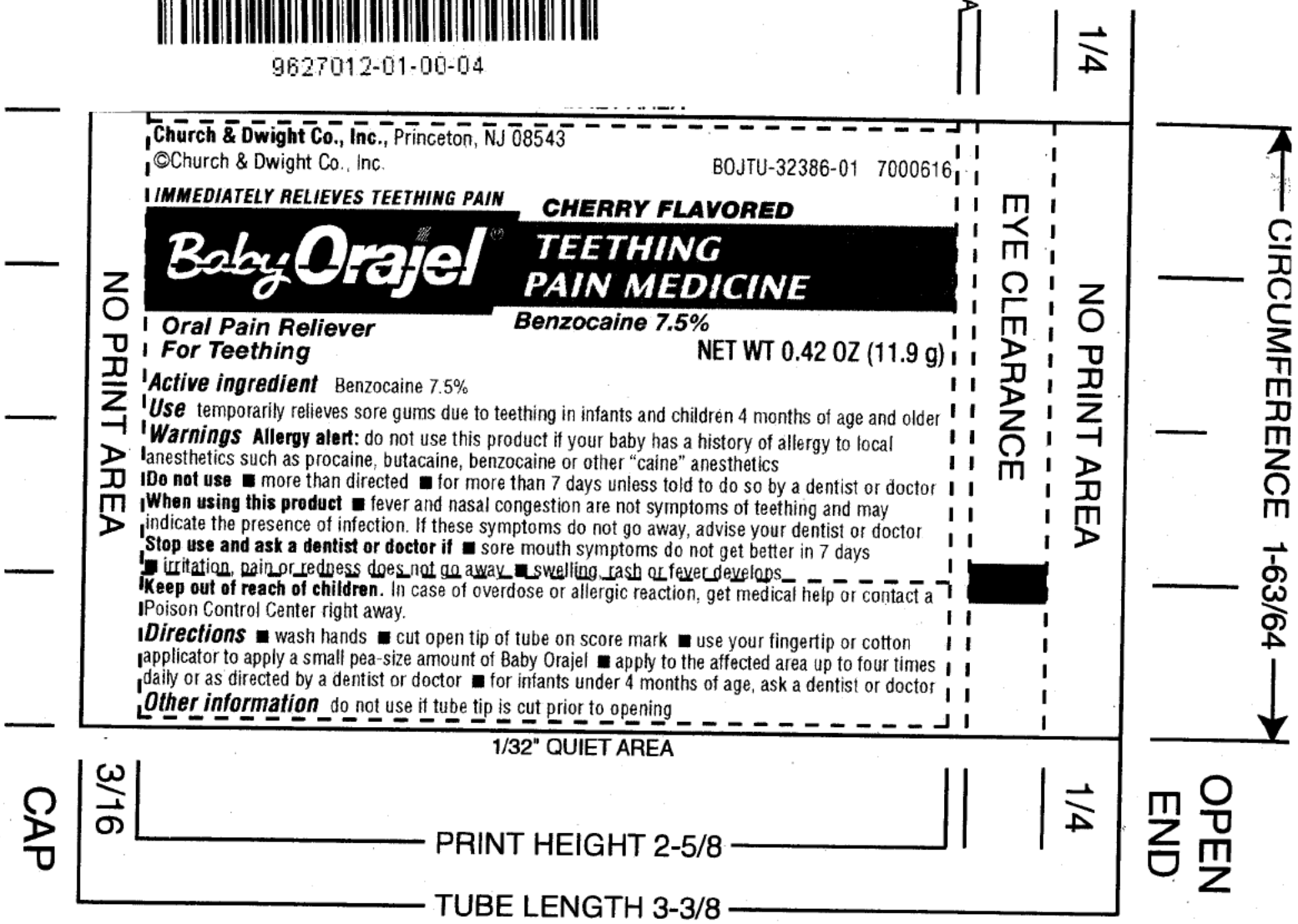
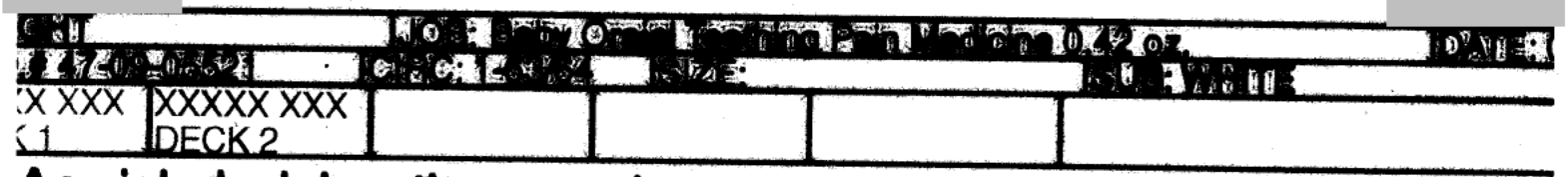
APPROVED for Copy, Content & Gra
By (b) (6) at 12:50 pm, Dec (

[redacted]



(b) (4)

(b) (4)



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Individual Case Safety Report

9627012-01-00-05

(b) (6)

Admission Information - Hospital Account/Patient Record

Arrival Date/Time:	None	Admit Date/Time:	(b) (6) 5:26 AM	IP Adm. Date/Time:	(b) (6) 5:26 AM
Admission Type:	Urgent	Admission Source:	Transfer From A Hospital (Different Facility)	Admit Category:	None
Means of Arrival:	Ambulance	Primary Service:	Pediatrics	Secondary Service:	None
Transfer Source:	(b) (6) Hospital	Service Area:	(b) (6)	Unit:	(b) (6)
Admit Provider:	(b) (6)	Attending Provider:	(b) (6)	Referring Provider:	(b) (6)

Final Diagnoses

Principal	Code	Name	POA	CC	HAC	Affects DRG
[P]	289.7	METHEMOGLOBINEMIA	Yes	CC		Yes
	518.81	ACUTE RESPIRATORY FAILURE	Yes	MCC		Yes
	802.36	OPEN FRACTURE OF SYMPHYSIS OF BODY OF MANDIBLE	Yes	CC		No

Discharge Information - Hospital Account/Patient Record

Discharge Date/Time	Discharge Disposition	Discharge Destination	Discharge Provider	Unit
(b) (6) 9:06 AM	Home Patient Family Member Other	Home	(b) (6) MD	(b) (6)

Events

Date/Time	Event	Pt Class	Unit	Room/Bed	Service
(b) (6) 0526	Admission	Inpatient	(b) (6)	(b) (6)	PED INTENSIVE CARE
0830	Surgery	Inpatient			E.N.T.
0854	Transfer Out	Inpatient			PED INTENSIVE CARE
0854	Transfer In	Inpatient			PED INTENSIVE CARE
0952	Transfer Out	Inpatient			PED INTENSIVE CARE
0952	Transfer In	Inpatient			PED INTENSIVE CARE
1626	Patient Update	Inpatient			PED INTENSIVE CARE
1024	Transfer Out	Inpatient			PED INTENSIVE CARE
1024	Transfer In	Inpatient			PED INTENSIVE CARE
1153	Patient Update	Inpatient			PED INTENSIVE CARE
1558	Transfer Out	Inpatient			PED INTENSIVE CARE
1558	Transfer In	Inpatient			Pediatrics
0906	Discharge	Inpatient			Pediatrics

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Allergies as of (b) (6) Date Reviewed: (b) (6)

H&P Summary Notes (continued)

HPI:

(b) (6) is a 2 year old male with history of recent mandible fracture after fall from 10ft retaining wall on (b) (6) who presented to (b) (6) Hospital with respiratory failure. He underwent maxillomandibular fixation on (b) (6) where his jaw was wired shut. He was discharged home on (b) (6) on clindamycin, tylenol #3, and motrin.

He had been doing well at home - playing in the yard, eating macaroni & cheese and hot dogs that mom could blend for him - until about 9pm on (b) (6) At that time, he began to complain of abdominal pain. His parents thought he was constipated, as he had not had a bowel movement since his surgery. They gave him a children's suppository, which did not help. At that point, dad left to go home. He received a phone call from (b) (6) mom at 2:30am stating that she was taking (b) (6) to the hospital because he was blue. Aside from being blue, (b) (6) was able to walk, talk, and scream.

Upon arrival to (b) (6) (b) (6) was bluish-purple colored. Oxygen saturations were in the 60s. His jaw wires were cut with wire cutters to allow for intubation. During RSI, immediately after receiving etomidate, (b) (6) did have some posturing that was attributed to administration of etomidate. He was successfully intubated, however, with bag-mask ventilation and PEEP of up to 8, oxygen saturations were in the high 70s to low 80s. His ABG after intubation was 7.38/36/153/99. Due to the outside facility's concern for PE, therapeutic lovenox at 1mg/kg was given in a one time dose prior to transfer.

It is of note that mom had been putting Orajel on his lips along with a moisturizer.

Past Medical History

Diagnosis — Date

- Asthma
- Prematurity

Past Surgical History:
Maxillomandibular Fixation on (b) (6)

Prior to Admission Medications:
No prescriptions prior to admission

Current Inpatient Medications:

Current facility-administered medications:

acetaminophen (TYLENOL) rectal suppository	60 mg	Rectal	Q4H PRN
D5W 1/2 NS 1000 mL with potassium chloride 20 mEq infusion		Intravenous	Continuous
vancomycin 5 mg/mL in D5W IV PEDS DILUTION 100 mg	10 mg/kg	Intravenous	Q6H
piperacillin/ tazobactam 100 mg/mL (of piperacillin) in D5W injection 800 mg	240 mg/kg/day	Intravenous	Q8H
heparin 1 Unit/mL in NS 60 mL premix PEDS line flush		Intravenous	Continuous
fentanyl (SUBLIMAZE) 50 mcg/mL injection	1 mcg/kg	Intravenous	Once
fentanyl (SUBLIMAZE) 50 mcg/mL PEDS	1 mcg/kg/hr	Intravenous	Continuous

(b) (6) (b) (6)

Operative Report (continued)

stable. The mouth was rinsed with Peridex. Two 26 gauge wires were then placed to bring the patient into mandibulomaxillary fixation, one on each side of the oral cavity. The patient was then allowed to awaken and extubated by anesthesia without incident. The patient tolerated the procedure well and there were no complications. Dr. (b) (6) was present for the entire case.

(b) (6) MD
Resident
(b) (6) Department of Otolaryngology

Electronically signed by (b) (6) MD at (b) (6) 1904

Discharge Instructions (b) (6) (MR # (b) (6))

None

Discharge Summary Notes

D/C Summaries signed by (b) (6) MD at (b) (6) 1015

Author: (b) (6) Service: (none) Author Type: Physician
MD
Filed: (b) (6) 1015 Note Time: (b) (6) 1651
Related Notes: Related Note by: (b) (6) MD filed at (b) (6) 0909
Original Note by: (b) (6) MD filed at (b) (6) 0909

(b) (6)

DISCHARGE SUMMARY

PATIENT NAME: (b) (6)
MRN: (b) (6)
DOB:

ADMISSION DATE: (b) (6)
DISCHARGE DATE:
ATTENDING PHYSICIAN: (b) (6)
PRIMARY CARE PHYSICIAN: (b) (6) MD

ADMISSION DIAGNOSIS: Methemoglobinemia
DISCHARGE DIAGNOSIS: Methemoglobinemia
Hospital Problems
Methemoglobinemia
Date Noted: (b) (6)

Respiratory failure
Date Noted: (b) (6)

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Resolved Hospital Problems
No resolved problems to display.

(b) (6)

(b) (6)

Discharge Summary Notes (continued)

Chronic Problems
Fall
Date Noted: 07/31/2011

Symphysis of body of mandible open fracture
Date Noted: 07/31/2011

Lacerations of face
Date Noted: 07/31/2011

Sacral Dimple
Date Noted: 03/12/2009

(b) (6) MD

DISCHARGE MEDICATIONS:
Current Discharge Medication List

CONTINUE these medications which have NOT CHANGED

acetaminophen (TYLENOL) 80 mg/0.8 mL Drop/Susp
take 160 mg by mouth Every 4 hours as needed.

acetaminophen-codeine (TYLENOL WITH CODEINE) 120-12 mg/5 mL Elix
take 4.48 mL by mouth Every 4 hours as needed.
Qty: 480 mL Refills: 0

clindamycin (CLEOCIN) 75 mg/5 mL SolR
take 5 mL by mouth once every 6 hours for 8 days.
Qty: 200 mL Refills: 0

ibuprofen (MOTRIN) 50 mg/1.25 mL Drop/Susp
take 2.8 mL by mouth Every 6 hours as needed.
Qty: 1 Bottle Refills: 1

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DISCHARGE INSTRUCTIONS:
No discharge procedures on file.

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REASON FOR HOSPITALIZATION AND HOSPITAL COURSE: This is a 2 y.o., male with history of recent mandible fracture after fall from 10ft retaining wall on (b) (6) who presented to (b) (6) Hospital with respiratory failure. He underwent maxillomandibular fixation on (b) (6) where his jaw was wired shut. He was discharged home on (b) (6) on clindamycin, tylenol #3, and motrin.

(b) (6)

LMR REPORT

(b) (6)

Discharge Summary Notes (continued)

He had been doing well at home - playing in the yard, eating macaroni & cheese and hot dogs that mom could blend for him - until about 9pm on (b) (6) At that time, he began to complain of abdominal pain. His parents thought he was constipated, as he had not had a bowel movement since his surgery. They gave him a children's suppository, which did not help. At that point, dad left to go home. He received a phone call from (b) (6) mom at 2:30am stating that she was taking (b) (6) to the hospital because he was blue. Aside from being blue, (b) (6) was able to walk, talk, and scream.

Upon arrival to (b) (6) (b) (6) was bluish-purple colored. Oxygen saturations were in the 60s. His jaw wires were cut with wire cutters to allow for intubation. During RSI, immediately after receiving etomidate, (b) (6) did have some posturing that was attributed to administration of etomidate. He was successfully intubated, however, with bag-mask ventilation and PEEP of up to 8, oxygen saturations were in the high 70s to low 80s. His ABG after intubation was 7.38/36/153/99. Due to the outside facility's concern for PE, therapeutic lovenox at 1mg/kg was given in a one time dose prior to transfer.

It is of note that mom had been putting Orajel on his lips along with a moisturizer.

DURING ADMISSION:

His work up in this hospital revealed an elevated methemoglobin level. He was given methylene blue and the symptoms resolved with improvement of saturations. ENT was consulted and his jaw was rewired for forced occlusion. He was given Tylenol & morphine for pain control.
He received vancomycin & zosyn for 2 days then was switched to clindamycin. He will continue the clindamycin at home.

CONDITION ON DISCHARGE:
A. Ambulation: ambulate well
B. Self-care Ability: taken care by mom.
C. Cognitive Status alert & oriented

DISCHARGE DISPOSITION: Home discharge

cc: Primary Care Physician:
(b) (6)

cc:Referring Physician:
(b) (6)

DSS
OCT 15 2013

(b) (6) MD

OCT 11 2013

Electronically signed by (b) (6) MD at (b) (6) 1015

(b) (6)

(b) (6)

Patient Education (continued)

Title: Patient Information Guide (Resolved) (continued)

Point: Speak Up Handout (Resolved)

Learning Progress Summary

Learner	Readiness	Method	Response	Comment	Given by	Status
Family	Acceptance	E	VU	Mom at bedside for rounds. See IPOC for plan of care. MOm stated understanding and denies any additional questions at this time.	(b) (6) (b) (6) 1224	Done

User Key

Initials	Effective Dates	Name	Provider Type	Discipline
(b) (6)	01/17/09 -	(b) (6) RN	Registered Nurse	Nurse

Ancillary Notes

Ancillary Notes signed by (b) (6) **MD at** (b) (6) **1358**

Author:	(b) (6) MD	Service:	Emergency	Author Type:	Resident
Filed:	(b) (6) 1358	Note Time:	(b) (6) 1346	Cosign Required:	Yes

Code Status: Full

No Known Allergies

Filed Vitals:

	(b) (6) 0400	(b) (6) 0600	(b) (6) 0700	(b) (6) 0800
BP:	74/44	69/49		72/34
Pulse:	91	74		83
Temp:	36.2 °C (97.2 °F)			36.4 °C (97.5 °F)
Resp:	20	37		19
Height:				
Weight:				
SpO2:	97%	97%	99%	98%

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HPI and Hospital Course:

In brief, patient is a 2 y.o. malewho presented to an outside facility with increase in duskiness of skin and was found to have very decreased saturations. He was recently treated operatively here at the beginning of (b) (6) for open mandibular fracture and in order to intubate at (b) (6) wires were cut. He was then transported here with decreased oxygen saturations. On arrival, blood gas showed greatly elevated methemoglobin levels. Methylene blue was given with

Ancillary Notes (continued)

significant improvement in respiratory status and complete resolution of methemoglobinemia on multiple blood gases. Upon presentation, we were also concerned for possible aspiration, and broad spectrum antibiotics were begun. ENT took patient to OR on (b) (6) for rewiring and patient extubated without difficulty post-operatively. Has had pain controlled with IV morphine here and was switched to PO Tylenol #3 today. Playing well. Tolerating IMF diet. ENT following and recommended de-escalation of antibiotics to Clindamycin. Patient started on PO Clindamycin. Although no specific culprit can be found, our working etiology for methemoglobinemia is his oralgel use at home.

Pertinent Exam Findings:
4 wires in place on jaw
Healing laceration at midline chin
No skin duskiness
Neurologically intact and appropriate

Pertinent Imaging/Lab results:
Methemoglobin 0.0

Pending Studies:
none

Consults:
ENT

Plan:
Resp: monitor. No need for continued ABG. Do not give oragel.
CV: stable
Neuro: interacting well. Monitor. PO pain control.
FEN/GI: IMF diet. UOP stable.
Heme/ID: PO clindamycin for prophylaxis. HH stable despite 2 recent surgeries.

Electronically signed by (b) (6) MD at (b) (6) 1358

Care Management Notes

Author: (b) (6) RN Service: (none) Author Type: CLINICAL CARE COORDINATOR

Filed: (b) (6) 1044 Note Time: (b) (6) 0528

Related Notes: Original Note by: (b) (6) RN filed at (b) (6) 1607

DSS
OCT 15 2013

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Patient Name: (b) (6)
DOB: (b) (6)
Age: 2
Account Number: (b) (6)
MR Number: (b) (6)

OCT 11 2013

==========

Admission Information
Encounter Type: Inpatient

Individual Case Safety Report

CaseID: 9630574

9630574-01-00-01

Report

Y reporting of
uct problems and
e errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 527516

The FDA Safety Information and
Adverse Event Reporting Program

Page 1 of 2

CDER

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	4 Months (b) (6)	☐ Female ☑ Male	15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☑ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/20/2007	10/16/2013

5. Describe Event, Problem or Product Use Error

when my son was four months old, I began giving him Hylands Teething Tablets. I gave him the recommended dose. As time progressed I noticed he would never put things in this mouth to teeth, didn't like spoons in his mouth and wasn't really babbling like most infants his age. I did continue giving him the Hylands Teething Tablets all the way through his 1-2 years. At the age of two we began noticing this blank staring spells where we'd almost have to shake him back to consciousness. We went to a development pediatrician because he was exhibiting flapping behaviors, food avoidance, not saying ...

6. Relevant Tests/Laboratory Data, Including Dates

EEG's performed in 2010 and 2013 both show conclusive results for absence seizures.
Genetic blood work 2011 to rule out Fragile X, Prader-Willi and any other genetic disorders.
Vineland assesments, ABBLS assessments and many other psychological assessments to conclude the Autism diagnosis and ...

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:White Medical Conditions: at the time of taking the teething tablets, his only known medical issue was jaundice at birth for which he spent four days under a billi ruben light. Allergies: eggs, cats, sulfa
Important Information: n/a RX Meds: at the time of the incident there were no medications ...

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

(1) #1 Name: Hyland's Teething Tablets
Strength:
Manufacturer:

OTC

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 pills	Four times daily	Taken by mouth
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/20/2007 - 10/20/2009
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething pain for infant/ toddler
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

CTU
OCT 16 2013

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
OCT 16 2013

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

... words and some fine motor delays. Our son was diagnosed with Autism in January of 2010 at 33 months of age. We are military and upon returning to the US in April of 2010 we took him in for an EEG and received a diagnosis of epilepsy with absence seizures occuring at a rate of 20 seizures every 10 minutes. He was placed on seizure medication and began ABA therapy and early intervention services for his Autism. He still at the age of six has oral motor issues, food avoidance and unable to speak. We have continued therapy, medication and intervention services to help with his Autism, Epilepsy and Oral Motor sensory issues. I pray to God that I did not poison my son with these teething tablets, however with reading other reports and seeing similar symptoms from other families, I am very concerned this product brought on not only my son's neurologicial issues, but his inablity to speak.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

... sensory issues.

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

... or medical devices being used. OTC Meds: only Hyland's teething tablets and Advil infant's motrin when needed.

F. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event) (continued)*

Individual Case Safety Report

9661367-01-00-01

Form Approved: OMB No. 0910-0291; Expires 12/31/11
See OMB statement on reverse.

Case ID: 982 [illegible]

er-facilities,
s and manufacturers
)RY reporting

of 23

Mfr Report #	2280705-2013-00065
UF/Importer Report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	8 Months	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		7.6 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
08/06/2012	10/29/2013

5. **Describe Event or Problem**

The patient experienced a desaturation event to the high 80's after his mother gave Orajel 15-20 times throughout the day. The methg level was elevated at >20% leading to the diagnosis of methemoglobinemia.

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Event occurred POD#2 after exploratory laparotomy and manual reduction of ileocolic intussusception.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*

#1 Orajel Instant Relief for Teething Pain

#2 (continued) 7.5% benzocaine

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 unk, 15-20 times, oral	#1 days prior to 08/04/2012
#2	#2 (cont'd) and 08/06/2012

4. **Diagnosis for Use** *(Indication)*

#1 [illegible] poisoning

#2

RECEIVED
OCT 30 2013
CDR

5. **Event Abated After Use Stopped or Dose Reduced?**

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. **Event Reappeared After Reintroduction?**

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC# or Unique ID**

10237-735

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Through hospital stay including (b) (6)
acetaminophen, lidocaine topical, morphine, diphenhydramine, medline solution, sodium chloride

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**

☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

DSS

10. **Device Available for Evaluation?** *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: OCT 31 2013 *(mm/dd/yyyy)*

11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone # (b) (6)
(b) (6)	OCT 30 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ◉ Unk.

☐ User Facility ☐ Importer

2. Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*
Lisa Burns
469 North Harrison Street
Princeton, NJ 08543
Church + Dwight Co, Inc

2. Phone Number
609-806-1997

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/15/2013

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/ 510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
methemoglobinemia

9. Manufacturer Report Number
2280705-2013-00065

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

A representative label of the product is attached. (pages 3, 4)

The pertinent pages of the hospital report are attached. (pages 5 through 23)

This report and information submitted under this report do not constitute an admission that the drug or Church & Dwight, Co. Inc. or any of its employees caused or contributed to the event described herein or that the event as reported to Church & Dwight Co., Inc actually occurred.

DSS
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9661367-01-00-03

#1 TEETHING BRAND recommended by Pediatricians

Orajel

Instant Relief for Teething Pain

cherry flavored gel

LONGER LASTING

SAFETY SEALED TUBE TIP

LONGER LASTING

NET WT 0.33 OZ (9.4g) GEL

ORAL PAIN RELIEVER FOR TEETHING BENZOCAINE 7.5%

3 10310 03313 2

Church & Dwight Co., Inc.
Princeton, NJ 08543

BOJFC-03313-04 1871695 70015598

NO INK O VARNISH

NO INK O VARNISH

To clean your baby's new teeth, try BABY ORAJEL® TOOTH & GUM CLEANSER

Drug Facts

Active Ingredient	Purpose
Benzocaine 7.5%	Oral pain reliever

Use for the temporary relief of sore gums due to teething in children 2 years of age and older. For use in children under the age of 2, consult a physician or healthcare provider.

Warnings

Allergy alert: do not use this product if your child has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use ■ more than directed ■ for more than 7 days unless directed by a physician or healthcare provider

When using this product ■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. if these symptoms persist, consult your physician.

Stop use and ask a physician if ■ sore mouth symptoms do not improve in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops

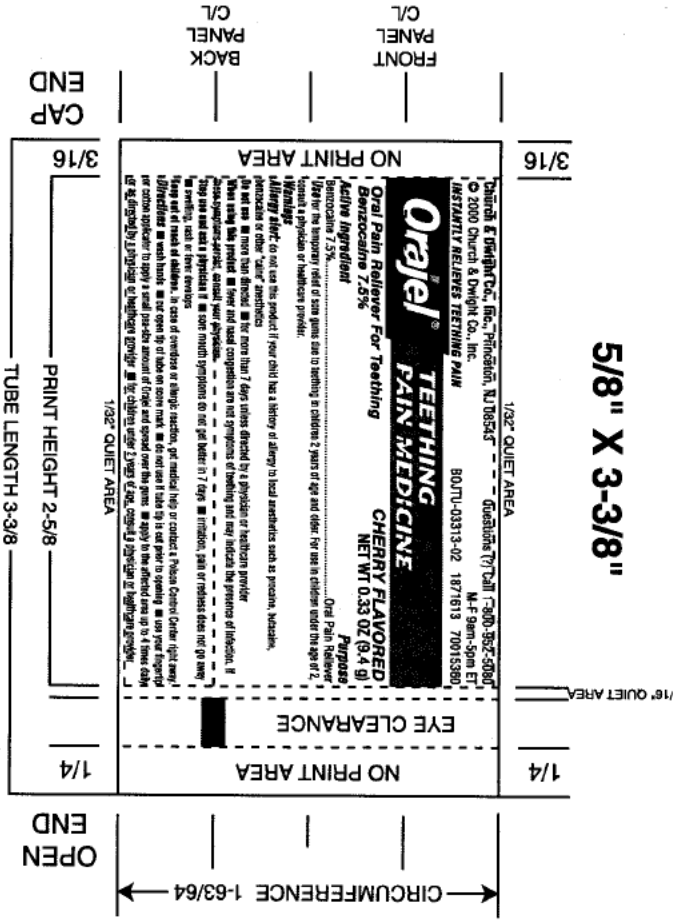
Keep out of reach of children.
In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions ■ wash hands ■ cut open tip of tube on score mark ■ use your fingertip or cotton applicator to apply a small pea-size amount of Orajel and spread over the gums ■ apply to the affected area up to 4 times daily or as directed by a physician or healthcare provider ■ for children under 2 years of age, consult a physician or healthcare provider

Other information do not use if tube tip is cut prior to opening

Inactive ingredients cellulose gum, flavor, gelatin, mineral oil, pectin, petrolatum, polyethylene glycol, red 40, sodium saccharin

Questions or comments? call us at 1-800-862-5060 M–F 9am–6pm ET or visit our website at www.orajel.com



(b) (6)

9661367-01-00-05

DOB: (b) (6)

FIN Nbr: (b) (6)

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

SIGNED BY:
(b) (6) ((b) (6) 23:36 PDT); (b) (6) ((b) (6) 04:53 PDT)

PICU CONSULTATION NOTE

PATIENT: (b) (6) **MRN:** (b) (6) **FIN:** (b) (6) **DOB:** (b) (6) **LOC:** (b) (6)

Admitting Service: General Surgery
Admitting Attending: (b) (6)
Date of Consultation: (b) (6)
Requesting Service: Peds Hospitalist_
Reason for Consultation: Hypoxia/methemoglobinemia_

Date of Admission: (b) (6)
Place of Consultation: (b) (6)
Requesting Physician: Dr. (b) (6)

IDENTIFICATION / CHIEF COMPLAINT: 8 month old with intussusception s/p open reduction without resection _

HISTORY OF PRESENT ILLNESS:
(b) (6) (goes by (b) (6)) is an 8 month old male (b) (6) from exploratory laparotomy and manual reduction of ileocolic intussusception. He has had an uncomplicated recovery until the afternoon of (b) (6) when he had a desaturation event to the high 80's. He was given supplemental oxygen via nasal cannula but continued to remain mildly hypoxic (while on up to 3L NC). The pulse oximetry probe was changed and his monitors were also changed but his hypoxia persisted with sats in low 90s. Of note, mom reports that he has had "teething" pain and was using orageI at home for comfort. She noticed that he was having similar discomfort yesterday and gave orageI approximately 15-20 times. The pediatric hospitalist was consulted at approx 0030 this morning for continued hypoxia and perioral cyanosis. Given the history of orageI use and possible benzocaine toxicity leading to methemglobinemia, a methg level was checked and was elevated at >20%.
I was called to consult on this patient given the diagnosis of methemoglobinemia, persiststent hypoxia, and the young age of the patient.

REVIEW OF SYSTEMS:
Constitutional: _
Eyes: _
ENT/Mouth: mild perioral cyanosis
Respiratory: breathing comfortably_
Cardiovascular: _
GI/Liver: _
Kidney/GU: _
Heme/Oncologic/Lymphatic: _
Musculoskeletal: _
Metabolic/Endocrine: _
Neurologic: _
Allergic/Immunologic: _
Skin: pale_
Development/Behavior: _

DSS
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Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

9661367-01-00-06

(b) (6)

al

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

Other: _

[_] A complete 14 system review performed; all systems are negative, except as documented.

PAST MEDICAL HISTORY:

1. Possible milk allergy - On Alimentum, scheduled to have allergy panel sent next week. Symptoms mostly GERD-like.
2. GERD - Diagnosed at 3 months of age. Changed formula several times and that seemed to help symptoms - never on medications.
3. Intussusception - See HPI. _

PAST SURGICAL HISTORY: Exploratory laparotomy and manual reduction of ileocolic intussusception, (b) (6) see HPI.

BIRTH HISTORY: Born FT via C-section due to breech presentation to 24 yo G1 P0->1 mom. Pregnancy and delivery uncomplicated. BW 6 lbs 1 oz. Home with mom after 3 days.

HOME DIET: Alimentum (s/p several formula changes, most recently from Enfamil Premium)

ACTIVE DIET ORDER(S):

Pedialyte: (b) (6) 16:58:00 PDT, PO, Comments: 0.5-1 ounce every hour

DEVELOPMENT: _

HOME MEDICATIONS:

No Home Medication/Prescription Orders

_

ACTIVE MEDICATION ORDERS (as of (b) (6) **04:04):**

Scheduled

acetaminophen 76 mg IV q4hr

PRN

acetaminophen 115 mg rectal q6hrPRN(discomfort/fever)
lidocaine topical 1 application topically as neededPRN(procedure)
morphine 0.25 mg IV q2hrPRN(pain)
diphenhydrAMINE 7.6 mg IV q6hrPRN(dry eyes)
medline solution 1 bag IV as neededPRN(protocol)
sodium chloride 1 mL IV as neededPRN(catheter care patency)

Continuous Infusion

Dextrose 5% with 0.45% NaCl and KCl 20 mEq/l 1000 mL IV

ALLERGIES: None recorded

DSS
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IMMUNIZATIONS: UTD per mom

FAMILY HISTORY: Dad with AR; mom with asthma as child.

SOCIAL HISTORY: Lives with mom, dad. No stick contacts, travel, or daycare.

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MEASUREMENTS:

Measured Weight: 7.6 kg ((b) (6) 04:20)

Approx. Percentiles

Weight: 4 %ile

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

9661367-01-00-07

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

Height: 72.5 cm (b) (6) 04:20) Height: 71 %ile

BMI: 14.459 kg/m2 (b) (6) 04:20) Wt for Length: 1 %ile

VITAL SIGNS OVER LAST 24 HOURS:

		(b) (6)
Temp	36.7 (36.1 - 36.7)	04:00
HR	106 (94 - 143)	04:02
Cuff BP	117/61 (86-118/49-72)	04:02
RR	21 (18 - 32)	04:02
SPO2	100 (88 - 100)	04:02

INTAKE & OUTPUT (Calculations based on current dose calc weight of 7.6 kg on (b) (6)):

	Previous 0600 - 0559		Since 0600	
Intake	1099.3 mL	144.6 mL/kg/24hrs	946.9 mL	124.6 mL/kg/22hrs
	953.6 mL Infusions		845.4 mL Infusions	
	101 mL Meds		41 mL Meds	
	45 mL Oral		60 mL Oral	
Output	828 mL	3.8 mL/kg/hr UOP	579 mL	3.2 mL/kg/hr UOP
	700 mL Urine		538 mL Urine	
	100 mL Gastric		41 mL Stool	
	28 mL Stool		1 Stool Count	
	1 Stool Count			
Balance	271.3 mL		367.9 mL	

PHYSICAL EXAM: **(Time of Exam: 0345_)**

General: [x] crying but easily consolable

Head: [x] NC/AT [x] AFOSF Other: _

Eyes: [x] PERRL [x] anicteric Other: _

ENT / Mouth: [x] clear oropharynx [_] TMs clear Other: lips- pink, no cyanosis_

Neck: [_x] supple

Lungs: [x_] clear [x] no distress Other: _

Cardiac: [x] reg rate & rhythm [x] no murmurs

Pulses: 2+ bilat fem_ Other: _

GI/Abdomen: [x] soft [_] non-tender [_] NL bowel sounds

[_] no hepatosplenomegaly Other: moderate distension, surgical site: c/d/i_

GU: [x] NL external genitalia Other: _

Extremities: [x] warm [x] no edema Capillary refill time: 2-3 sec Other: _

Neurologic: [_] non focal/grossly intact Other: _

Skin: [x] no rashes/lesions Other: _

Other: _

DSS
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RADIOLOGY STUDIES (Completed):

XR Chest 1 View (b) (6) 02:20 _

OCT 30 2013

Print Date/Time: 12/11/2012 14:26 PST **Report Request ID:** (b) (6)

9661367-01-00-08

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

LABS:

CHEM 23 (within 36 hours):

```
 136   |  104   |  <5 L  /          8.7        AST:        GGT:
-------+--------+--------- 92       \ /        ALT:        LDH:
 4.6   |   28   | 0.4 H  \           |         ALKP:       TChol:
                                                ALB:        TG:
Chem: (b) (6)  01:50        (b) (6)  01:50      TP:
TBili:                                          Globulin:
DBili:                                          UA:
```

CBC w/Diff (within 36 hours):

```
        \  11.2  /          PMN:
  13.4   --------- 646 H     Bands:
        /  33.5  \           Lymph:
                             Mono:
Last CBC: (b) (6)  01:50     Eos:
CRP:                         Meta:
                             Baso:
```

OTHER RESULTS: _

Microbiology Results Updated in Last 48 Hours (Collect Date/Time Shown):
No microbiology results found.

ASSESSMENT / PLAN: 8 mo M s/p exploratory laparotomy for manual reduction of ileocolic intussusception now with methemoglobinemia likely from benzocaine toxcitity. Pt had received a dose of methylene blue prior to my arrival. on exam, he did not have any signs of cyanosis (lips were pink) and his 02 sats were 99% on 1L NC. when weaned to room air, he maintained his O2 sat>99%. He was hemodynamically stable, appeared comfortable, and was tolerating pedialyte from his bottle. His chest xray was concerning for possible LLL atelectesis and some mild edema but was otherwise WNL.

Recommendations at this time:

1) contact poison control for further assistance
2) recheck a methemoglobin level in 3-4 hrs. consider redose of methylene blue if still >15-20%
3) continue oxygen supplementation to keep O2 sat >96%
4) given his rapid improvement, he will be safe to monitor in (b) (6) at this time. we will check in again with the next lab draw. please feel free to contact us if he has any more episodes of desaturations and we will transfer him to the PICU for closer monitoring.

This plan was discussed with the parents at bedside.

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[x] I have discussed my recommendation with the requesting physician _

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PATIENT CARE TIME: "Only applicable if counseling or coordination time (C) is > 50% of total visit time (V):"
(V) Total attending face to face and floor/unit time with patient and/or family: _ (minutes)

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

9661367-01-00-09

(b) (6)

tal

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

(C) Total attending Counseling/Coordination time with patient and/or family: _ (minutes)
Describe the counseling performed: _

Report prepared by: (b) (6) MD

Teaching Physician Attestation

I saw and examined the patient and discussed his/her management with the resident/fellow. I reviewed the resident/fellow's note and agree with the documented findings and plan of care. Care plan, managment and recommendations discussed with fellow as described above. On re-evaluation at bedside pt had received methylene blue with return to saturaiton of 100% and resolution of cyanosis. Re-check level and treat if inidcated. Would not hesitate to transfer to PICU for evidence of further decline._

Entered by (b) (6) *MD on* (b) (6) *23:35*

DSS
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Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

9661367-01-00-10

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

SIGNED BY:
(b) (6) ((b) (6) 03:56 PDT);(b) (6) L ((b) (6) 03:23 PDT); (b) (6) ((b) (6) 02:10 PDT)

Addendum by (b) (6) **MD,** (b) (6) **on** (b) (6) **03:56 PDT**
Elevated methemoglobin percent indicative of methemoglobinemia.

Called Poison Control and spoke with (b) (6) - he initially recommended checking repeat methemoglobin levels every 4 hours and giving subsequent methylene blue doses every 4 hours until the methemoglobin level is less than 5. He called back to revise his recommendations to repeat methemoglobin levels only if symptomatic. I informed him that we had already discussed q4 levels with mom, and given the parental anxiety this evening I will still check a level in 4 hours (at around 0630) (b) (6) recommended giving a subsequent dose of methylene blue in that case only if the repeat level is >20, or if symptomatic.

I spoke with Dr. (b) (6) PICU fellow, several times over the course of the evening, and he was in contact with his attending Dr. (b) (6) We discussed possible PICU transfer given the risk of hypoxia and clinical decompensation in such a young infant with methemoglobinemia, but upon recheck at 0335 at the bedside with Dr. (b) (6) O2 saturations on room air were 97-98%, his lips were pink, and he continued to have no respiratory distress. We therefore agreed to not transfer to the PICU, but continue monitoring him on the floor.

Spoke with Dr. (b) (6) of Surgery several times during the evening, and paged her with our final plan at 0345.

Updated mom several times throughout the evening, and updated mom and dad with Dr. (b) (6) at 0335. Also updated bedside and charge RN throughout the evening.

ATTENDING MD DOCUMENTATION & ATTESTATION:
This patient is critically ill with a high probability of imminent or life-threatening deterioration. He requires constant monitoring and critical care interventions under my direct supervision for the following organ system(s): [x] Respiratory [x] Metabolic [_] CNS [_] Renal [_] Circulatory [_] Hepatic/GI [_] Heme/Bone Marrow [_] Immunologic [_] _ system(s) [_] to treat organ failure, and/or [_] to prevent further life-threatening deterioration.

I saw and examined this patient and discussed his management with the team. I drafted the above note. I have discussed these plans with staff at the bedside.
Entered by (b) (6) *MD on* (b) (6) *03:51*

Time Based Care - Counseling IP
Only applicable if counseling or coordination time (C) is > 50% of total visit time (V):
(V) Total attending face to face and floor/unit time with patient and/or family: additional 90 minutes CCT (minutes)
(C) Total attending Counseling/Coordination time with patient and/or family: 70 (minutes)
Describe the counseling performed: see documentation above

DSS
OCT 31 2013

~~*Entered by* (b) (6) *MD on* (b) (6) *03:51*~~

Addendum by (b) (6) **on** (b) (6) **2012 03:23 PDT**
GASES (within 1 day(s)):
Venous (b) (6) *01:50)* 7.38 / 48.3 / 20.2 / 28.0 / 3.3 Methemoglobin % 20.2

OCT 30 2013

Print Date/Time: 12/11/2012 14:26 PST **Report Request ID:** (b) (6)

Individual Case Safety Report

CaseID: 9661367

9661367-01-00-11

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

CHEM 10 (within 36 hours):

```
 136   |  104   |  <5 L  /          8.7
-------+--------+--------- 92       \ /
 4.6   |   28   | 0.4 H  \           |
```

Chem: (b) (6) 01:50 (b) (6) 01:50

CBC w/Diff (within 36 hours):

```
       \  11.2  /          PMN:
  13.4  ---------- 646 H   Bands:
       /  33.5  \          Lymph:
                           Mono:
Last CBC: (b) (6) 01:50    Eos:
```

(b) (6) **0220 CXR:** Final read pending. Appears to have increased vascularity. No consolidation.

GENERAL PEDIATRICS CONSULT NOTE

PATIENT: (b) (6) **MRN:** (b) (6) **FIN:** (b) (6) **DOB:** (b) (6) **LOC:** (b) (6)

Admitting Service: General Surgery
Admitting Attending: (b) (6)
Date of Consultation: (b) (6) 0110
Requesting Service: Pediatric Surgery
Reason for Consultation: Hypoxia

Date of Admission: (b) (6)
Place of Consultation: (b) (6)
Requesting Physician: Dr. (b) (6)

DSS
OCT 31 2013

IDENTIFICATION / CHIEF COMPLAINT: 8 month old with intussusception s/p open reduction without resection

HISTORY OF PRESENT ILLNESS: (b) (6) is an 8 month old boy with a history of possible milk allergy and GERD who is (b) (6) s/p exploratory laparotomy and manual reduction of ileocolic intussusception, who has had recent onset of hypoxia. He initially presented with 6-7 days of vomiting, diarrhea, and hematochezia to an outside hospital, where an ultrasound showed intussusception. He was transferred to (b) (6) ED, where a repeat ultrasound also showed intussusception. Air contrast enema x 4 was unsuccessful at reduction, and he was therefore treated surgically. The procedure was uncomplicated, and his recovery was apparently uneventful until he started to desaturate (b) (6) and appear pale. The surgical team first attributed this to oversedation from his morphine. His morphine dose was therefore decreased from 0.5 to 0.25 mg q 2 hrs. At around 2200 on (b) (6) he was noted to desaturate to the high 80s, and nursing contacted the surgical team who ordered oxygen to be given via nasal canula. His oxygen saturations remained in the low 90s per nursing, despite trying several pulse oximetry probes and even changing out his monitor. Though he has had some mild congestion since (b) (6) and some red eyes (sclerae and eyelids), he has not had any significant rhinorrhea, cough, tachypnea, or increased work of breathing. He has been afebrile, and he has been active and alert per mom. He has been a little fussy and "gnawing" on his hands, which mom has attributed to teething pain. He has not been sleepier than usual. She had been giving him Oragel occasionally at home for a couple days prior to admission, but notes that she used it much more frequently (b) (6) (estimates 15-20 times over the course of the day). Looking back, she does note that she thought his lips looked a little purple on the afternoon of (b) (6) I was contacted at around 0030 this morning by the Oncology resident because of concern for methemoglobinemia.

REVIEW OF SYSTEMS:

OCT 30 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

9661367-01-00-12

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

Constitutional: See HPI.
Eyes: No eye discharge. See HPI. + "Poking" at eyes.
ENT/Mouth: See HPI.
Respiratory: See HPI.
Cardiovascular: No concerns
GI/Liver: No vomiting. Now stooling regularly - no evidence of gross blood.
Kidney/GU: No concerns
Heme/Oncologic/Lymphatic: No concerns
Musculoskeletal: No concerns
Metabolic/Endocrine: No concerns
Neurologic: No seizures
Allergic/Immunologic: No concerns
Skin: No rash. See HPI.
Development/Behavior: See HPI
[x] A complete 14 system review performed; all systems are negative, except as documented.

PAST MEDICAL HISTORY:
1. Possible milk allergy - On Alimentum, scheduled to have allergy panel sent next week. Symptoms mostly GERD-like.
2. GERD - Diagnosed at 3 months of age. Changed formula several times and that seemed to help symptoms - never on medications.
3. Intussusception - See HPI.

PAST SURGICAL HISTORY: Exploratory laparotomy and manual reduction of ileocolic intussusception, (b) (6) - see HPI.

BIRTH HISTORY: Born FT via C-section due to breech presentation to 24 yo G1 P0->1 mom. Pregnancy and delivery uncomplicated. BW 6 lbs 1 oz. Home with mom after 3 days.

HOME DIET: Alimentum (s/p several formula changes, most recently from Enfamil Premium)

ACTIVE DIET ORDER(S):
Pedialyte: (b) (6) 16:58:00 PDT, PO, Comments: 0.5-1 ounce every hour

HOME MEDICATIONS:
Oragel prn

ACTIVE MEDICATION ORDERS (as of (b) (6) **01:13):**

DSS
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Scheduled
acetaminophen 76 mg IV q4hr

PRN
acetaminophen 115 mg rectal q6hrPRN(discomfort/fever)
diphenhydrAMINE 7.6 mg IV q6hrPRN(dry eyes)
lidocaine topical 1 application topically as neededPRN(procedure)
medline solution 1 bag IV as neededPRN(protocol)
morphine 0.25 mg IV q2hrPRN(pain)
sodium chloride 1 mL IV as neededPRN(catheter care patency)

Continuous Infusion
Dextrose 5% with 0.45% NaCl and KCl 20 mEq/l 1000 mL IV

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ALLERGIES: NKDA

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

9661367-01-00-13

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

IMMUNIZATIONS: UTD per mom

FAMILY HISTORY: Dad with AR; mom with asthma as child.

SOCIAL HISTORY: Lives with mom, dad. No stick contacts, travel, or daycare.

MEASUREMENTS:

Measured Weight: 7.6 kg ((b) (6) 04:20)
Height: 72.5 cm ((b) (6) 04:20)
BMI: 14.459 kg/m2 ((b) (6) 04:20)

Approx. Percentiles

Weight: 4 %ile
Height: 71 %ile
Wt for Length: 1 %ile

VITAL SIGNS OVER LAST 24 HOURS:

		(b) (6)
Temp	36.1 (36.1 - 36.7)	23:45
HR	114 (94 - 143)	23:50
Cuff BP	95/56 (86-107/41-57)	23:50
RR	29 (15 - 32)	23:50
SPO2	91 (88 - 99)	23:50

INTAKE & OUTPUT (Calculations based on current dose calc weight of 7.6 kg on (b) (6)):

	Previous 0600 - 0559		Since 0600	
Intake	1099.3 mL 953.6 mL Infusions 101 mL Meds 45 mL Oral	144.6 mL/kg/24hrs	810.9 mL 725.4 mL Infusions 25 mL Meds 60 mL Oral	106.7 mL/kg/19hrs
Output	828 mL 700 mL Urine 100 mL Gastric 28 mL Stool 1 Stool Count	3.8 mL/kg/hr UOP	579 mL 538 mL Urine 41 mL Stool 1 Stool Count	3.7 mL/kg/hr UOP
Balance	271.3 mL		231.9 mL	

PHYSICAL EXAM: (b) (6) 0100

General: Sleeping peacefully, awoke with exam, briefly fussed with abdominal exam
Head: NCAT, AFOSF
Eyes: Bilateral eyelids a little dusky, no conjectival injection or discharge
ENT / Mouth: MMM and mildly dusky. No anterior oropharyngeal lesions. No nasal discharge or audible congestion
Neck: Supple, no significant LAD or mass.
Lungs: RR high 20s, no retractions or distress, no grunting or nasal flaring, lungs CTAB, no w/c/r, no stertor/stridor
Cardiac: RRR, + 1/6 soft systolic murmur at LUSB, brachial and femoral pulses +2
GI/Abdomen: Normoactive BS, abdomen mildly-to-moderately distended but soft, incision steri-stripped without evidence of erythema or discharge
GU: Tanner I male
Extremities: Wwp, CR < 2 sec centrally, 2-3 sec palms and soles
Neurologic: Good tone, good eye contact; no focal deficits
Skin: No rash. Right palm a little ruddy. Lips, tongue, and mucous membranes mildly dusky. No additional plethora or cyanosis.

Individual Case Safety Report

CaseID: 9661367

14 of 23

9661367-01-00-14

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Inpatient Consultation

Other: Helped hold patient for venipuncture at 0150 - blood from right AC appeared dark, not copperish)

RADIOLOGY STUDIES (Completed): No Radiology studies found within the last 24 hours.

LABS:

CHEM 23 (within 36 hours):

```
 139   |  106   |  <5 L  /          8.8
-------+--------+-------- 92        \ /
 5.2   |   27   |  0.3   \           |
```

Chem: (b) (6) 06:40 (b) (6) 06:40

ASSESSMENT / PLAN: (b) (6) is an 8 month old boy with a history of possible milk allergy and GERD who is (b) (6) (b) (6) s/p exploratory laparotomy and manual reduction of ileocolic intussusception, who has had recent onset of hypoxia. His hypoxia seems to be refractory to supplemental oxygen, and he has possible mild central cyanosis with a history of very frequent Benzocaine administration, making methemoglobinemia a concern. With his recent surgery and general anesthesia, he is also at risk for atelectasis, aspiration, and pneumonia. His lack of respiratory distress, retractions, and adventitious breath sounds would argue against this, as would the timing (would expect symptoms sooner after surgery). My recommendations are as follows:

-- Methemoglobin level STAT
-- VBG with co-ox STAT
-- CBC STAT
-- CXR portable STAT

[x] I have discussed my recommendation with the requesting physician Dr. (b) (6)

PATIENT CARE TIME: "Only applicable if counseling or coordination time (C) is > 50% of total visit time (V):"

(V) Total attending face to face and floor/unit time with patient and/or family: 90 (minutes)

(C) Total attending Counseling/Coordination time with patient and/or family: 60 (minutes)

Describe the counseling performed: Discussion with notifying Oncology resident, discussion with bedside and charge nurse regarding status and work-up, obtained history from mom and provided several updates, assisted holding patient during venipuncture.

Report prepared by: (b) (6) MD

DSS
OCT 31 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

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Individual Case Safety Report

CaseID: 9661367

15082

9661367-01-00-15

(b) (6)

Patient Name: (b) (6)

MRN: (b) (6)

DOB:

FIN Nbr: (b) (6)

Admit/Reg Date: n/a

Discharge Date: n/a

Discharge Summary

SIGNED BY:
(b) (6) 17:14 PDT); (b) (6) 09:51 PDT)

PEDIATRIC SURGERY DISCHARGE SUMMARY

PATIENT: (b) (6) **MRN:** (b) (6) **FIN:** (b) (6) **DOB:** (b) (6) **LOC:** (b) (6)

Admitting Service: General Surgery
PCP: (b) (6)
Admitting Attending: (b) (6)

Date of Admission: (b) (6)
Discharge Date: (b) (6)
Operating Attending Surgeon:

ADMITTING DIAGNOSIS: _ intussusception

PRINCIPAL DIAGNOSIS: _ same

SECONDARY DIAGNOSES: methemoglobinemia

PAST MEDICAL HISTORY: _ none

PAST SURGICAL HISTORY: _ none

PATIENT IDENTIFICATION: 8 month old with intussusception s/p open reduction without resection _

PRINCIPAL OPERATION(S) / PROCEDURES:
operative reduction of intussusception

CONSULTATIONS THIS ADMISSION: _ Hospitalist

DETAILED HOSPITAL COURSE:
(b) (6) is an 8 mo boy who presented with 6 days of bloody diarrhea, abdominal distention and pain and was found to have intussusception on abdominal ultrasound at an (b) (6) He was transferred here and intussusception was confirmed on repeat US at (b) (6) Reduction with barium enema was attempted four times unsuccesfully and he was taken to the OR for operative reduction of intussusception. He was hypokalemic on admission and his potassium was repleted to normal with a potassium of 5.1 at discharge. On the evening of (b) (6) he was markedly pale and desated to the high 80s on room air. The pediatric hospitalist service was consulted and suspected methemoglobinemia after it was discovered that mom had been giving him Orajel 15-20 times per day for teething pain. His methomoglobin level was found to be 20.2 and he was given methylene blue. His sats subsequently came back up to 99-100% on room air and remained normal on room air. He was tolerating feeds, had resolution of abdominal distention and pain was well controlled on the day of discharge.

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PATIENT CONDITION UPON DISCHARGE: _ stable, tolerating feeds, pain controlled
Last Documented Weight: 7.6 kg ((b) (6) 04:20) _

Discharge Vital Signs:

Temp	37.4	(b) (6)	04:00
HR	145		04:00

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Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

Individual Case Safety Report

CaseID: 9661367

9661367-01-00-16

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Discharge Summary

Cuff BP	100/55	(b) (6)	04:00
RR	26		04:00
SPO2	98		04:00

PHYSICAL EXAM: _ (Time of Exam: _)

General: [x] no acute distress Other: _

Head: [x] NC [_] AFOSF Other: _

ENT /Mouth: [_] clear oropharynx [_] moist mucous membranes Other: _

Eyes: [_] PERRL [_] anicteric Other: _ EOMI

Neck: [x] supple [_] no LAD Other: _

Lungs: [_] clear [_] no distress Other: _

Cardiac: [_] reg rate & rhythm [_] no murmurs [_] pulses Other: _

GI/Abdomen: [x] soft, non-tender, non-distended [_] no masses Other: _

GU: [_] NL external genitalia Other: _

Extremities: [x] warm [_] no edema Capillary refill time: _ Other: _

Neurologic: [x] non focal/grossly intact Other: _

Skin: [_] no rashes/lesions Other: _

Wound / Ostomy / Line / Drain: _

Other: _

DISCHARGE MEDICATIONS:
No Home Medication/Prescription Orders

_

DIET / FEEDS UPON DISCHARGE: _ feeds ad lib

PHYSICAL ACTIVITY: _ as tolerated

SPECIFIC INSTRUCTIONS GIVEN TO PATIENT UPON DISCHARGE: _ follow-up in Pediatric General Surgery clinic in 1 month

Bathing/Incision: _ can bathe, wash incisions gently with soap and water

FOLLOW UP CARE: _
[x] A Pediatric General Surgery Clinic Appointment has been requested for the patient. The family will be contacted by the clinic to schedule.
[_] PMD/Other services: _
Other: _
Please call the Pediatric General Surgery Office at (b) (6) with any questions.

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External CC:
CONTACT INFORMATION:

Print Date/Time: 12/11/2012 14:26 PST **Report Request ID:** (b) (6)

Individual Case Safety Report

CaseID: 9661367

17023

9661367-01-00-17

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Discharge Summary

SIGNED BY:
(b) (6) (b) (6) 01:56 PDT)

(b) (6)

DSS
OCT 31 2013

OCT 30 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

Individual Case Safety Report

CaseID: 9661367

180623

9661367-01-00-18

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Discharge Summary

Referring MD: (b) (6)

(b) (6)

Primary Care Provider: (b) (6)

(b) (6)

Other: _

Report prepared by: (b) (6) MD

Teaching Physician Attestation

I saw and examined the patient and discussed his/her management with the resident/fellow. I reviewed the resident/fellow's note and agree with the documented findings and plan of care. _

Entered by (b) (6) *MD on* (b) (6) *17:14*

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Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Discharge Summary

SIGNED BY:
(b) (6) ((b) (6) 09:51 PDT)

Discharge Record Form Entered On: (b) (6) 09:56 PDT
Performed On: (b) (6) 09:51 PDT by (b) (6)

DC Record Form
Discharge Date : (b) (6) PDT
Attending MD on Day of Discharge : (b) (6)
Admission Date : (b) (6) PDT
Admitting Diagnosis : intussusception
Principal Diagnosis : intussusception
Principal Operations/Procedures : operative reduction of intussusception
Brief Hospital Course Summary : Admitted on (b) (6) with intussusception on abdominal ultrasound. Attempted to reduce with barium enema 4 times unsuccessfully. Taken to OR for operative reduction of intussuception. Desats to high 80s on (b) (6) found to have methemoglobinemia with methemoglobin level 20.2. Given methylene blue with return to normal oxygen saturations on room air. Discharged (b) (6) tolerating feeds and pain controlled.

Condition of Patient at Discharge : Stable
Disposition of Patient : Home
Med Reconciliation Completed for D/C : Yes
Medication List at Discharge : See "DC Instructions" for list of patient's current meds
Location of Discharge Rx Script : Electronically sent to pharmacy
Diet upon Discharge : Formula
Discharge Diet Instructions : Continue home feeding regimen
Physical Activity upon Discharge : No physical limitations
Instructions for Follow-up Care : We will call to schedule an appointment to follow-up in Pediatric General Surgery clinic in 1 month
DC Summary Record Ready to Print : Yes

(b) (6) . (b) (6) 09:51 PDT [Not Validated]

Med Reconciliation
Medication List
Normal Order

Acetaminophen 80mg/2.5mL oral prepack	: Acetaminophen 80mg/2.5mL oral prepack ; Status: Ordered ; Ordered As Mnemonic: Tylenol oral ; Simple Display Line: 80 mg, 2.5 mL, PO, q6hr, PRN: discomfort/fever ; Ordering Provider: (b) (6) Catalog Code: acetaminophen ; Order Dt/Tm: (b) (6) 20:50 ; Comment: *** Do not administer any acetaminophen containing products within 4 hours of each other. *** Standardized dosing Ordered dose: 100mg Dispensed dose: 80mg
Acetaminophen 80mg/2.5mL oral prepack	: Acetaminophen 80mg/2.5mL oral prepack ; Status: Ordered ; Ordered As Mnemonic: Tylenol oral ; Simple Display Line: 80 mg, 2.5 mL, PO, q4hr, PRN: fever/chills ; Ordering Provider:

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Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

9661367-01-00-20

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Discharge Summary

	(b) (6) Catalog Code: acetaminophen ; Order Dt/Tm: (b) (6) 10:30 ; Comment: *** Do not administer any acetaminophen containing products within 4 hours of each other. *** Standardized dosing Ordered dose: 76mg Dispensed dose: 80mg
DiphenhydraMINE 50 mg/mL inj	: DiphenhydraMINE 50 mg/mL inj ; Status: Ordered ; Ordered As Mnemonic: Benadryl pediatrics ; Simple Display Line: 7.6 mg, 0.15 mL, IV, q6hr, PRN: dry eyes ; Ordering Provider: (b) (6) (b) (6) Catalog Code: diphenhydrAMINE ; Order Dt/Tm: (b) (6) 16:56
Acetaminophen 10 mg/mL inj	: Acetaminophen 10 mg/mL inj ; Status: Discontinued ; Ordered As Mnemonic: acetaminophen IV ; Simple Display Line: 76 mg, 7.6 mL, IV, q4hr ; Ordering Provider: (b) (6) (b) (6) Catalog Code: acetaminophen ; Order Dt/Tm: (b) (6) 11:01 ; Comment: *** Do not administer any acetaminophen containing products within 4 hours of each other. ***
Acetaminophen 325 mg suppository	: Acetaminophen 325 mg suppository ; Status: Ordered ; Ordered As Mnemonic: acetaminophen rectal ; Simple Display Line: 115 mg, 0.35 supp, rectal, q6hr, PRN: discomfort/fever ; Ordering Provider: (b) (6) Catalog Code: acetaminophen ; Order Dt/Tm: (b) (6) 09:30 ; Comment: *** Do not administer any acetaminophen containing products within 4 hours of each other. *** *** No rectal dosage forms for neutropenic patients ***
Lidocaine 4% topical cream 5 gm	: Lidocaine 4% topical cream 5 gm ; Status: Ordered ; Ordered As Mnemonic: lidocaine 4% topical cream ; Simple Display Line: 1 application, topically, as needed, PRN: procedure ; Ordering Provider: (b) (6) Catalog Code: lidocaine topical ; Order Dt/Tm: (b) (6) 09:30
medline solution	: medline solution ; Status: Ordered ; Ordered As Mnemonic: medline solution ; Simple Display Line: 1 bag, IV, as needed, PRN: protocol ; Ordering Provider: (b) (6) Catalog Code: medline solution ; Order Dt/Tm: (b) (6) 09:30 ; Comment: MEDLINE SOLUTIONS are for administration of an IV medication if no other compatible hydration fluid is ordered. Refer to the Medication Administration Guidelines or check with pharmacy for compatibility info.

DSS

OCT 31 2013

OCT 30 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

21823

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Discharge Summary

Morphine 2 mg/mL inj prefilled syringe	: Morphine 2 mg/mL inj prefilled syringe ; Status: Ordered ; Ordered As Mnemonic: morphine ; Simple Display Line: 0.25 mg, 0.13 mL, IV, q2hr, PRN: pain ; Ordering Provider: (b) (6) (b) (6) Catalog Code: morphine ; Order Dt/Tm: (b) (6) 09:30
Sodium Chloride 0.9% 10 mL prefilled syringe	: Sodium Chloride 0.9% 10 mL prefilled syringe ; Status: Ordered ; Ordered As Mnemonic: NS lock ; Simple Display Line: 1 mL, IV, as needed, PRN: catheter care patency ; Ordering Provider: (b) (6) Catalog Code: sodium chloride ; Order Dt/Tm: (b) (6) 09:30 ; Comment: *** Use to lock PIV catheter after use and at least every 8 hours *** *** Refer to (b) (6) Vascular access chart for additional information ***
Dextrose 5%-NACL 0.45%-KCL 20mEq/L 1,000 mL	: Dextrose 5%-NACL 0.45%-KCL 20mEq/L 1,000 mL ; Status: Discontinued ; Ordered As Mnemonic: D5 1/2 NS + KCl 20 mEq/L 1,000 mL ; Simple Display Line: 40 mL/hr, IV, Stop: (b) (6) 9:28:00 PDT ; Ordering Provider: (b) (6) Catalog Code: Dextrose 5% with 0.45% NaCl and KCl 20 m ; Order Dt/Tm: (b) (6) 09:30
Prescription/Discharge Order acetaminophen	: acetaminophen ; Status: Ordered ; Ordered As Mnemonic: Tylenol Childrens 160 mg/5 mL oral liquid ; Simple Display Line: 114 mg, PO, q4hr, 120 mL, PRN: for pain ; Ordering Provider: (b) (6) Catalog Code: acetaminophen ; Order Dt/Tm: (b) (6) 09:55

DSS

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OCT 30 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

Individual Case Safety Report

CaseID: 9661367

9661367-01-00-22

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Outpatient/Clinic Documents

SIGNED BY:
(b) (6) (b) (6) 06:22 PDT); (b) (6) (b) (6) 12:44 PDT)

PATIENT NAME: (b) (6)
MRN: (b) (6)
DATE OF BIRTH: (b) (6)

CLINIC: General Surgery
VISIT DATE: (b) (6)
ATTENDING CLINICIAN: (b) (6) MD
RESIDENT PHYSICIAN: (b) (6) MD

HISTORY OF PRESENT ILLNESS: (b) (6) returns to the Pediatric Surgery Clinic at (b) (6) Children's Hospital for a follow-up visit after his recent operative reduction of his nonreducible intussusception performed on (b) (6) (b) (6) His postoperative course was complicated in the hospital by methemoglobinemia due to Orajel poisoning, given erroneously in excess for teething pain by his mother. After being given methylene blue to correct his methemoglobin level, his oxygen saturations on room air returned to 99% to 100%, and by the day of discharge on (b) (6) he was tolerating feeds, had resolution of his abdominal distention and his pain was well controlled.

Since discharge, his mother states that (b) (6) has been gaining weight and has been very active and healthy. He has had a return to normal bowel function, and has been eating solid foods since his discharge. He has had no fevers, does not appear to be in any sort of abdominal distress, and his incision has continued to heal well. The mother has noticed no swelling or redness in the area of the incision.

PHYSICAL EXAMINATION:
VITAL SIGNS: He weighs 9 kg, his temperature is 36.7 degrees Celsius.
GENERAL: He is a well-appearing, healthy child, who is smiling and active during the examination.
ABDOMEN: Revealed a well-healing transverse surgical incision over the medial and right aspect of his mid abdomen. His abdomen was soft, nontender to palpation, and nondistended.

IMPRESSION AND PLAN: (b) (6) mother was advised that his postoperative course appears to be uncomplicated and (b) (6) appears to be healing quite well. The mother was instructed that should any questions or concerns arise, that she should feel free to call the clinic and schedule a return visit should the need arise; however, at this time there should be no need for any further scheduled visits.

(b) (6) MD

(on behalf of)

(b) (6) MD

DSS
OCT 31 2013

(b) (6)

D: (b) (6) 02:04 P
T: 11:57 P

OCT 30 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

9661367-01-00-23

(b) (6)

Patient Name: (b) (6)

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: n/a

Discharge Date: n/a

Outpatient/Clinic Documents

I: (b) (6) 12:04 A

Teaching Physician Attestation

I saw and examined the patient and discussed his/her management with the resident/fellow. I reviewed the resident/fellow's note and agree with the documented findings and plan of care.

Entered by (b) (6) *MD on* (b) (6) *06:22*

Electronically signed on (b) (6) 12:44

(b) (6), BS Medical Student

Electronically signed on (b) (6) 06:22

(b) (6)

DSS

OCT 31 2013

OCT 30 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID: (b) (6)

Individual Case Safety Report

9747541-01-00-01

...er-facilities,
...rs and manufacturers
...ORY reporting

Form Approved: OMB No. 09-19-0291; Expires 12/31/11
See OMB statement on reverse.

CaseID: 9747541

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 6

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 6 Months or Date of Birth:
3. Sex: ☑ Female ☐ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: ____ (mm/dd/yyyy)
- ☐ Life-threatening
- ☑ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 11/11/2013

4. Date of This Report (mm/dd/yyyy): 11/21/2013

5. Describe Event or Problem

ON 11/10/13, CHILD EXPERIENCED LOSS OF APPETITE, LETHARGY AND WEAKNESS AND WAS DIAGNOSED WITH AN EAR INFECTION. ON (b) (6) CHILD BECAME UNRESPONSIVE AND TAKEN TO HOSPITAL AND PUT IN ICU. CHILD IS LETHARGIC AND SLEEPING CONTINUOUSLY. (b) (6) CHILD PLACED ON FEEDING TUBE. (b) (6) CHILD HAD CHOKING EPISODE AND STOPPED BREATHING AND PUT ON BREATHING TUBE. POSSIBLE BELLADONNA POISONING PER DOCTORS BUT RUNNING TESTS TO DETERMINE OTHER POSSIBLE CAUSES OF SYMPTOMS.

(b) (6) UPDATE: CHILD HAS BEEN DIAGNOSED WITH INFANT BOTULISM. CHILD WILL BE GIVEN ONE DOSE OF MEDICATION WHICH IS COMPOSED OF HUMAN ANTIBODIES.

6. Relevant Tests/Laboratory Data, Including Dates

BLOOD, URINE, CHEST X-RAY, SPINAL TAP, CT SCAN, EEG, AND MRI WHICH WAS NORMAL. WAITING ON RESULTS OF TESTS.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

PRESCRIBED ANTIBIOTICS FOR AN EAR INFECTION ON 11/10/13.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
- #1 HYLAND'S BABY TEETHING TABLETS
- #2 HYLAND'S TEETHING TABLETS

2. Dose, Frequency & Route Used
- #1
- #2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
- #1
- #2

4. Diagnosis for Use (Indication)
- #1 TEMP RELIEF TEETHING SXS/PAIN
- #2 TEMP RELIEF TEETHING SXS/PAIN

5. Event Abated After Use Stopped or Dose Reduced?
- #1 ☐ Yes ☐ No ☑ Doesn't Apply
- #2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #
- #1 UNKNOWN
- #2 UNKNOWN

7. Exp. Date
- #1
- #2

8. Event Reappeared After Reintroduction?
- #1 ☐ Yes ☐ No ☑ Doesn't Apply
- #2 ☐ Yes ☐ No ☑ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1//54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model # | Lot # | Catalog # | Expiration Date (mm/dd/yyyy) | Serial # | Other #

5. Operator of Device
- ☐ Health Professional
- ☐ Lay User/Patient
- ☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

DSS DEC 06

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6) USA

Phone #

DEC 05 2013

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

DEC 0

Initial Reporter Also Sent Report to FDA? ● Yes ☐ No ☐ Unk

Individual Case Safety Report

CaseID: 9747541

FDA USE ONLY

9747541-01-00-02

of 6

1. Check One: ☐ User Facility ☐ Importer

2. Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report: ☐ Initial ☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
11/14/2013

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 AE # 1517

8. Adverse Event Term(s)
EXTREME LETHARGY, WEAKNESS, CHOKING, HOSPITALIZATION

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: _____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: _____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: _____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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DEC 0 5 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Ca[illegible]7541

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: 2527

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 11/14/13

PRODUCT: BABY TEETHING TABLETS // TEETHING TABLETS

ITEM CODE: BTET // TEET

SIZE: UNKNOWN

LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS:

RECEIVED

DEC 04 2013

CDR

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #:

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER POSTED ON (b) (6) THAT ON NOV. 10 CHILD EXPERIENCED LOSS OF APPETITE, LETHARGY AND WEAKNESS. 11/10/13: CHILD DIAGNOSED WITH AN EAR INFECTION AND PRESCRIBED ANTIBIOTICS. (b) (6) CHILD BECAME UNRESPONSIVE AND TAKEN TO HOSPITAL AND PUT IN ICU. CHILD IS EXTREMELY LETHARGIC AND SLEEPING CONTINUOUSLY. (b) (6) CHILD PLACED ON FEEDING TUBE. (b) (6) CHILD HAD CHOKING EPISODE AND STOPPED BREATHING AND PUT ON BREATHING TUBE. POSSIBLE BELLADONNA POISONING PER DOCTORS, BUT RUNNING TESTS TO DETERMINE CAUSE OF SYMPTOMS. SEE ATTACHED POSTINGS.
TESTS: BLOOD, URINE, X-RAY CHEST, SPINAL TAP, CT SCAN, EEG, AND MRI WHICH WAS NORMAL. WAITING FOR RESULTS OF TESTS. URL ADDRESS:
(b) (6) (b) (6)
(b) (6)

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

11/20/13 UPDATE: CHILD DIAGNOSED WITH INFANT BOTULISM. CHILD WILL BE TREATED WITH ONE DOSE OF MEDICATION COMPOSED OF HUMAN ANTIBODIES.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/14/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

Individual Case Safety Report

9747541-01-00-03

DATE:

DSS

DEC 062

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1517

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/14/13 BY: EDYTA FRACKIEWICZ

DEC 05 20

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 11-27-13

BY: QA / QC DIRECTOR DATE: 11-27-13

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE 134

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum was "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

11/26/13
Date

Individual Case Safety Report

9747541-01-00-04

DS
DEC 06

DEC 05 2

AE # 1517
Complaint # 2527
CC-0790-2013
AE-0491-2013
SAE-0052-2013

CaseID: 9747541

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1517 **COMPLAINT #:** 2527

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

Individual Case Safety Report

9747541-01-00-05

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DS
DEC 0

SECTION IV:

REVIEWED BY MANAGEMENT BY: PW DATE: 11-27-13

BY: QA / QC DIRECTOR DATE: 11-27-13

DEC 0 5 20

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

CaseID: 9747541

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1517 COMPLAINT #: 2527

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9747541-01-00-06

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
DEC 06 2

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

BY: Eric Baum DATE: 11-27-13
QA / QC DIRECTOR

DEC 05 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

9767440-01-00-01

...y user-facilities,
...utors and manufacturers
...ATORY reporting

Form Approved: OMB No. 09...Expires ...
See OMB Statement on reverse

CaseID: 9767440

Mfr Report # 54973 See page 2

UF/Importer Report #

FDA Use On...

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	8 Months	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/09/2013	10/16/2013

5. Describe Event or Problem

HAD 8 SMALL "SEIZURES" LASTING A COUPLE OF SECONDS. EYES ROLLED BACK INTO HEAD, WAS DRROOLING, AND HEAD JERKED LEFT AND RIGHT. CHILD HAS NEVER EXPERIENCED THESE TYPES OF SYMPTOMS.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

TAKES GENERIC VERSION OF CLARITIN LIQUID FOR PET HAIR ALLERGY (AS NEEDED).

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration from/to (or best estimate)*
#1 2 TABS UNDER TONGUE	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF SX IRRITABILITY

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Does... Apply

#2 ☐ Yes ☐ No ☐ Does... Apply

6. Lot #	7. Exp. Date
#1 B06813	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Does... Apply

#2 ☐ Yes ☐ No ☐ Does... Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

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NOV 06 2013

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone # (b) (6)
(b) (6)	

USA

2. Health Professional?	3. Occupation	4. Initial Reporter Also Se... Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ◉ Un...

NOV 05 2013

9767440-01-00-02

CaseID: 9767440

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | 5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)* | 7. Type of Report ☐ Initial ☐ Follow-up # ____ | 8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device | 10. Event Problem Codes *(Refer to coding manual)* Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/09/2013

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973 AE # 1513

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Ca... 7440

SECTION I: COMPLAINT

COMPLAINT #: 2522

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 10/10/13

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: B06813

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

RECEIVED
NOV 05 2013
CDR

NATURE OF COMPLAINT: SON IS 8 MONTHS OLD. MOTHER GAVE 2 TABLETS FOR THE FIRST TIME LAST NIGHT 10/09/13 AROUND 7:30 PM AND AROUND 9:30 PM HAD 8 SMALL "SEIZURES" LASTING A COUPLE OF SECONDS. EYES ROLLED BACK INTO HEAD, WAS DROOLING, AND HEAD JERKED LEFT AND RIGHT. CHILD HAS NEVER EXPERIENCED THESE TYPES OF SYMPTOMS. NO FEVER, NO ILLNESS. TAKES AN ALLERGY MEDICINE FOR ALLERGY TO PET HAIR (GENERIC FOR CLARITIN LIQUID) – BUT DID NOT USE LAST NIGHT. NO HISTORY OF HEAD INJURY. HAS NOT CONTACTED THE DOCTOR. TOLD HER NOT TO USE THE TABLETS AND TO CONTACT HER DOCTOR.
FOLLOW-UP 10/11/13: CUSTOMER CALLED BACK TO PROVIDE LOT NUMBER.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

Individual Case Safety Report

9767440-01-00-03

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/10/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1513

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/10/13

BY: EDYTA FRACKIEWICZ

DSS
NOV 06 2013

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 10-25-13

BY: Eric Bauer
QA / QC DIRECTOR

DATE: 10-22-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

NOV 05 2013

9767440-01-00-04

9767440

SE EVENT DATA FORM

AE #: 1513 **COMPLAINT #:** 2522

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

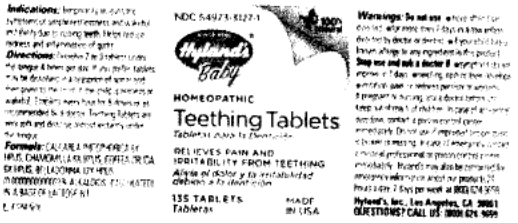
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

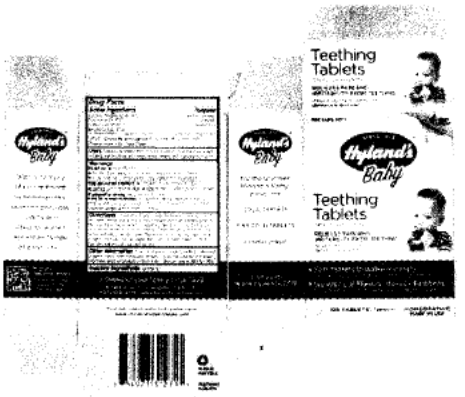
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-25-13

BY: QA / QC DIRECTOR DATE: 10-22-13

DSS
NOV 06 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

NOV 05 2013

9767440-01-00-05

ANDARD
OPATHIC
HE USA SINCE 1903

Serious Adverse Event
SAE-0048-2013

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot #B06813, are currently in the Standard Homeopathic Co. (SHC) warehouse. All but 7 units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B06813 was manufactured using bulk lot # 120102. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B06813. Additionally, the Baby Teething bulk lot # 121015 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # B06813.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B06813.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

10/22/13
Date

DSS
NOV 06 201

CC-0685-2013
AE-0414-2013
SAE #130
AE #1513
Complaint #2522

NOV 05 2013

Individual Case Safety Report

9790085-01-00-01

CaseID: 9790085

OTC CDER

or VOLUNTARY reporting of
rse events, product problems and
product use errors

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

The FDA Safety Information and
Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 535038

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event or Date of Birth: DOB: (b) (6)	3. Sex	4. Weight
		☐ Female ☒ Male	23 lb 10 oz or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☒ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☒ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
11/30/13	12/16/13

5. Describe Event, Problem or Product Use Error
Parents gave ~~food~~ 2 teething tablets and put him down for nap. Abnormal breathing noted during nap - grunting, squirming, wouldn't wake for >10min. Eval in ED concerning for seizure.

6. Relevant Tests/Laboratory Data, Including Dates
Influenza (neg)
RSV (neg)

CTU
DEC 30 2013

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
~~None~~ Did have fever for 1-2 days prior to event. Diagnosed with ear infection that day.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☒ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hyland's Teething Tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 tablets	once	by mouth
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 11/29 - 11/30
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2 Fussiness

6. Lot #	7. Expiration Date
#1 unknown	#1 unknown
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ ~~Doesn't~~ Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name | 2b. Procode DSS

3. Manufacturer Name, City and State | DEC 30 2013

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)* | 7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
Tylenol
Ibuprofen

G. REPORTER *(See confidentiality section on back)*

1. Name and Address: (b) (6)
Name:
Address:
City:
Phone #

2. Health Professional?	3. Occupation	4. Also Reported to:
☒ Yes ☐ No	Physician	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☒

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

9820308-01-00-01

CaseID: 9820308

ER

t Consumer Report

UNTARY reporting of ts, product problems and oduct use errors

OTC

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence # 536227

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	5 Months (b) (6)	☐ Female ☑ Male	12 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☑ Death: (b) (6) *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
12/02/2013	01/10/2014

5. **Describe Event, Problem or Product Use Error**

After using Hyland Teething Tablets on my 5 mo old grandson for the first time he died in his sleep. When they found him he had a temp of 102 and cause of death is Accute Cardio Pulminary Arrest I believe this was caused by these teething tablets!!!! After reading the effects of Belladonna used in these tablets I am almost sure there is a link to my grandson's death and these tablets. SOMEONE NEEDS TO INVESTIGATE THIS!!!!!

6. **Relevant Tests/Laboratory Data, Including Dates**

Autopsy is pending

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:White

Medical Conditions:

Allergies:

Important Information:

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*

#1 Name: Hyland Teething Tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 12/02/2013 -
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 Teething pain and uncomfort
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** CTU

3. **Manufacturer Name, City and State** JAN 13 2014

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	**Other #**	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
(b) (6)

DSS
JAN 13 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

9924670-01-00-01

Health Professional Report

CDER

VOLUNTARY reporting of events, product problems and product use errors

1/1

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

CaseID: 9924670

FDA USE ONLY
Triage unit sequence # 540891

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. **Patient Identifier**: (b) (6) In confidence
2. **Age at Time of Event or Date of Birth**: 4 Months (b) (6)
3. **Sex**: ☑ Female ☐ Male
4. **Weight**: _____ lb or 7.2 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*: 02/22/2014

4. **Date of this Report** *(mm/dd/yyyy)*: 02/22/2014

5. **Describe Event, Problem or Product Use Error**
infant admitted due to profound flushing and irritability withut obvious cause had been on Hylands Teething Tablest for the last week at 3 tablets per day.

6. **Relevant Tests/Laboratory Data, Including Dates**
complete metabolic panel, CRP, Abd X-rays and X- ray of right leg normal. WBC 20.2 with normal differential.

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
Term infaant with vaccines current, previously well after short stay in NICU for low apgar.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*

#1 Name: hyland's teething tablets
Strength: homeopathic
Manufacturer: Hyland's Inc

#2 Name:
Strength:
Manufacturer:

2. **Dose or Amount** / **Frequency** / **Route**

#1: 3 tabs / QD / Oral

#2:

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*

#1 02/14/2014 - 02/22/2014

#2

4. **Diagnosis or Reason for Use** *(Indication)*

#1 teething

#2

5. **Event Abated After Use Stopped or Dose Reduced?**

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**

#1 A 97113

#2

7. **Expiration Date**

#1

#2

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**: CTU

2. **Common Device Name**: FEB 24 2014

3. **Manufacturer Name, City and State**

4. **Model #**

Lot #

Catalog #

Expiration Date *(mm/dd/yyyy)*

Serial #

Other #

5. **Operator of Device**
☐ Health Professional
☐ Lay User/Patient
☐ Other: _____

6. **If Implanted, Give Date** *(mm/dd/yyyy)*

7. **If Explanted, Give Date** *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*
Tylenol infant drops

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
(b) (6)

DSS

Phone #: (b) (6)

E-mail: (b) (6) FEB 24 20

2. **Health Professional?**: ☑ Yes ☐ No

3. **Occupation**: Medical Doctor (Physician)

4. **Also Reported to:**
☐ Manufacturer
☐ User Facility
☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

Individual Case Safety Report

CDER

CaseID: 9998991

9998991-01-00-01

et Consumer Report

LUNTARY reporting of
nts, product problems and
product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

The FDA Safety Information and
Adverse Event Reporting Program

1/2

FDA USE ONLY
Triage unit sequence # 542709

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	27 Weeks (b) (6)	☑ Female ☐ Male	13 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/07/2014	03/09/2014

5. **Describe Event, Problem or Product Use Error**

I purchased Hyland's Baby Teething Tablets for my seven month old daughter. After giving her two tablets under her tongue she began to cry incessantly, like never before. She spiked a fever of 101, 10 minutes after receiving the tablets and refused to nurse. She developed a rash on her cheeks that reminded me of chicken pox. She was throwing up all her milk, and was grabbing at her arms and legs as if they hurt. I have never seen my daughter act this way, or scream in such pain. She was up for three hours in my arms screaming, and finally passed out. I had assumed she was sick at first and it ...

6. **Relevant Tests/Laboratory Data, Including Dates**

NA

CTU
MAR 11 2014

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:White

Medical Conditions: NA

Allergies: NA

Important Information: PRETERM baby born at 37 weeks gestation

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*

#1 Name: Hyland's Teething Tablets
Strength: Does not say
Manufacturer: Hyland's, Inc. Las Angeles, CA

OTC

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2-3 tablets 4 times per day	Four times daily	Taken by mouth
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 03/07/2014 – 03/08/2014
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 7 month old with teething pain
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 B36913	#1	54973-3127-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. **If Implanted, Give Date** *(mm/dd/yyyy)* 7. **If Explanted, Give Date** *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
(b) (6)

DSS
MAR 11

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

... did not even cross my mind that the tablets could have caused her symptoms. But the next night I gave her two more before bed and she was in tears, fever and rash again. I then thought maybe she could have an allergic reaction to the tablets so looked them up on the internet, what I found was extremely alarming. I have no doubt in my mind that Hyland's Baby Teething Tablets had very negative side effects on my daughter.

Individual Case Safety Report

9998991-01-00-02

Individual Case Safety Report

CaseID: 9999086

9999086-01-00-01

net Consumer Report

)LUNTARY reporting of
ents, product problems and
product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 54 2782

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	5 Months (b) (6)	☐ Female ☑ Male	19 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:
1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/07/2014	03/08/2014

5. Describe Event, Problem or Product Use Error

We gave our 5 month old Hylands Teething tablets Friday afternoon/evening. Friday at 10pm he projectile vomited everywhere. He vomited again about 30 minutes later. We did not know it was the tablets. The next day at noon we gave him the tablets again. The same result ensued. We then learned about the issues with the Hylands product and ceased dosage. He is slowly recovering, but certainly still not feeling well. He is having trouble taking full feedings.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:White

Medical Conditions: N/A

Allergies: Wheat, Soy

Important Information: N/A

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hylands Teething Tablets
Strength: N/A
Manufacturer: Hylands, Inc.

OTC

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 tablets	Four times daily	Taken by mouth
#2		

3. Dates of Use *(if unknown, give duration) from/to (or best estimate)*
#1 03/07/2014 - 03/08/2014
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 Infant teething
#2

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 B43013	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

MAR 11 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: (b) (6)
Address:
City: State: -- ZIP:

DSS
MAR 11

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

10023432-02-00-01

OTC

user-facilities
ors and manufacturers
TORY reporting

CaseID: 10023432

Form Approved: OMB No. 0910-0291, Expires 12/3
See OMB statement on rev

MFR Report # 54973 5-20 page 2

UF/Importer Report #

FDA Use

FORM FDA 3500A (8/10)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	6 Months	☐ Female	17 lbs
In confidence	or Date of Birth:	☑ Male	or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
11/22/2013 -- 12/04/2013	12/10/2013

5. Describe Event or Problem

CHILD DIAGNOZED WITH INFANTILE SPASMS. ALSO POSSIBLE SEIZURE LIKE ACTIVITY RELATED TO GASTROESOPHAGEAL REFLUX (SANDIFER'S SYNDROME) BUT HAS NOT BEEN CONFIRMED. CHILD WAS HOSPITALIZED ON (b) (6) AND PLACED ON ZANTAC AND ACTHAR.

6. Relevant Tests/Laboratory Data, Including Dates

GENETIC AND METABOLIC TESTS, LUMBAR PUNCTURE, MRI, URINE TEST NORMAL. EEG CONFIRMED INFANTILE SPASMS.

Received
FEB 04 2014
CDR

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD BORN 3 - 4 WEEK PREMATURE.

(b) (6) EAR INFECTION. GIVEN AUGMENTIN.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give durati from/to (or best estimate)*
#1 2-3TABS UP TO TID INTERM	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF OF TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Do Ap
#2	#2 ☐ Yes ☐ No ☐ Do Ap

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A97113	#1	#1 ☐ Yes ☐ No ☐ Do Ap
#2	#2	#2 ☐ Yes ☐ No ☐ Do Ap

9. NDC# or Unique ID: 54973-3127-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Devi
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Profess
Serial #	Other #	☐ Lay User/Patie
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone # (b) (6)
(b) (6)	

DSS
FEB 05 2014

2. Health Professional?	3. Occupation	4. Initial Reporter Also Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ●

FEB 04 2014

Individual Case Safety Report

CaseID: 10023432

10023432-02-00-02

of 10

FDA USE ONLY

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code _____ – _____ – _____

Device Code _____ – _____ – _____

11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address ***(and Manufacturing Site for Devices)***

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
12/09/2013

5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☑ Follow-up # 1

8. Adverse Event Term(s)
INFANTILE SPASMS

9. Manufacturer Report Number
54973 AE # 1521

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: _____

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*

Method _____ – _____ – _____ – _____

Results _____ – _____ – _____ – _____

Conclusions _____ – _____ – _____ – _____

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: _____

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or **11.** ☐ **Corrected Dat**

Received
FEB 04 2014
CDR

DSS
FEB 04 2014
FEB 05 2014

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

OMB Statement:
"An agency may not conduct or spo
and a person is not required to resp
to, a collection of information unless
displays a currently valid OMB conti
number."

Please DO NOT RETURN this form to this address.

Individual Case Safety Report

CaseID: 10023432

10023432-02-00-03

PLAINT RECORD

COMPLAINT #: 2531

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 12/09/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T250

SIZE: 250 TABLETS

LOT NO.: A97113

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GIVING CHILD 11/20/13 3 TABLETS AT BEDTIME AND THEN THE NEXT DAY HUSBAND GAVE 1 TABLET A FEW TIMES AND THEN THAT DAY THE CHILD STARTLED IN HIS CAR SEAT AND WAS SHORT OF BREATH (A FRIEND NOTICED IT). 11/22/13: SHE USED THE TEETHING TABLETS 2 TABLETS ABOUT 3 TIMES THAT DAY. CHILD BECAME FUSSY THAT DAY AND SHE PUT HIM IN THE CAR SEAT AND HE STARTED CRYING AND HAVING SPASMS (SHE DESCRIBES IT AS AN EXAGGERATED MORO REFLEX). REACHES OUT ARMS AND CRYS OUT LIKE A STARTLE REFLEX WHICH WAS COMING IN CYCLES. THE CYCLES WOULD LAST MAYBE A MINUTE AND HAVING 6 OR 7 EPISODES. (b) (6) WOKE UP AND HAD THESE EPISODES AND MOM TOOK HIM TO THE ER. AT THE ER THEY FOUND AN EAR INFECTION AND GAVE HIM AN ANTIBIOTIC (AUGMENTIN). THERE WAS NO FEVER. 11/25/13: WENT TO THE PEDIATRICIAN WITH A SICK CALL AND SHE VIDEOTAPED THE EPISODE AND THE NURSE PRACTITIONER SAID IT WAS A SEIZURE LIKE ACTIVITY RELATED TO GASTROESOPHAGEAL REFLUX (SANDIFER'S SYNDROME) BUT SHE HAS NOT FOLLOWED UP WITH HAVING AN ENDOSCOPY TO CONFIRM. SHE WENT HOME AND CHILD WAS HAVING MORE CYCLES UP TO 8 PER DAY. MOTHER CONTINUED TO GIVE CHILD MORE TEETHING TABLETS DURING THIS TIME (CARIOUS DOSES). ON (b) (6) MOTHER WENT BACK TO ER, AND THE DOCTOR SAID THAT THE CHILD WOULD BE ADMITTED TO THE HOSPITAL. PEDIATRIC NEUROLOGIST CAME IN AND THEY DID EEG AND CONFIRMED "INFANTILE SPASMS". THIS IS RECOGNIZED UNDER THE EPILEPSY DIAGNOSIS. CHILD IS ON ZANTAC AND ACTHAR (FOR SEIZURES). LAST DOSE OF TEETHING TABLETS WAS 12/04/13. MOTHER HEARD ABOUT THE RECALL THE OTHER DAY AND HAS CONNECTED THE INFANTILE SPASMS WITH THE TEETHING TABLETS. LAST SPASM WAS ON 12/04/13. SHE IS GOING TO TALK TO THE NEUROLOGIST ABOUT THE TEETHING TABLETS. CHILD IS BOTTLE FED. WAS PREMATURE BY 3 – 4 WEEKS. OUR PHARMACIST, EDYTA FRACKIEWICZ, TOLD THE MOTHER THAT IT'S POSSIBLE HER CHILD COULD BE SENSITIVE OR ALLERGIC TO THE TEETHING TABLETS OR SYMPTOMS COULD BE DUE TO SOMETHING ELSE. TOLD HER THAT IF EFFECT IS A TRANSIENT HOMEOPATHIC EFFECT THEN THE SYMPTOMS SHOULD RESOLVE AFTER PRODUCT IS DISCONTINUED. I OFFERED HER A REFUND FOR THE TEETHING TABLETS AND SHE ACCEPTED. PAID $10.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 12/09/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACIEWICZ

SECTION III: **CORRECTIVE ACTION:**

12/10/13 (b) (6) PREPARED REFUND REQUEST TOTALING $ 15.79. 12/27/13 (b) (6) MAILED REFUND CHECK # 511188 TOTALING $ 15.79 ON ARTICLE # 70081830000486288153.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6)

DATE: 12/10/13 & 12/27/13

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1521

DSS

ADVERSE EVENT SERIOUS: (Y) / N

FEB 05 2014

ADVERSE EVENT REPORTED ON: 12/09/13

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

FEB 04 2014

DATE: 01-23-14

BY: Erica Bacci
QA / QC DIRECTOR

DATE: ~~01 22 13~~ EJB 01-23 01-23-14 for 01-22-14

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VD1

Individual Case Safety Report

10023432-02-00-04

CaseID: 10023432

DARD HOMEOPATHIC

December 10, 2013

Received
FEB 04 2014
CDR

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $ 14.39. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $ 15.79

DSS
FEB 05 2014

FEB 04 2014

Standard Homeopathic Company · Setting the Standard in Homeopathy, Since 1903
210 West 131st Street · Box 61067 · Los Angeles, CA 90061 · (213) 321-4284 · fax (310) 516-8579
P.O. Box 87 · Bryn Mawr, PA 19010 · (215) 520-0580 · fax (215) 520-0582

Individual Case Safety Report

10023432-02-00-06

CaseID: 10023432

mb 12/17/13

COMPLAINT RECORD

Hyland's

COMPLAINT #: 2531

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 12/09/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T250

SIZE: 250 TABLETS

LOT NO.: A97113

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL: (b) (6)

NATURE OF COMPLAINT: GIVING CHILD 11/20/13 3 TABLETS AT BEDTIME AND THEN THE NEXT DAY HUSBAND GAVE 1 TABLET A FEW TIMES AND THEN THAT DAY THE CHILD STARTLED IN HIS CAR SEAT AND WAS SHORT OF BREATH (A FRIEND NOTICED IT). 11/22/13: SHE USED THE TEETHING TABLETS 2 TABLETS ABOUT 3 TIMES THAT DAY. CHILD BECAME FUSSY THAT DAY AND SHE PUT HIM IN THE CAR SEAT AND HE STARTED CRYING AND HAVING SPASMS (SHE DESCRIBES IT AS AN EXAGGERATED MORO REFLEX). REACHES OUT ARMS AND CRYS OUT LIKE A STARTLE REFLEX WHICH WAS COMING IN CYCLES. THE CYCLES WOULD LAST MAYBE A MINUTE AND HAVING 6 OR 7 EPISODES. (b) (6) WOKE UP AND HAD THESE EPISODES AND MOM TOOK HIM TO THE ER. AT THE ER THEY FOUND AN EAR INFECTION AND GAVE HIM AN ANTIBIOTIC (AUGMENTIN). THERE WAS NO FEVER. 11/25/13: WENT TO THE PEDIATRICIAN WITH A SICK CALL AND SHE VIDEOTAPED THE EPISODE AND THE NURSE PRACTITIONER SAID IT WAS A SEIZURE LIKE ACTIVITY RELATED TO GASTROESOPHAGEAL REFLUX (SANDIFER'S SYNDROME) BUT SHE HAS NOT FOLLOWED UP WITH HAVING AN ENDOSCOPY TO CONFIRM. SHE WENT HOME AND CHILD WAS HAVING MORE CYCLES UP TO 8 PER DAY. MOTHER CONTINUED TO GIVE CHILD MORE TEETHING TABLETS DURING THIS TIME (CARIOUS DOSES). ON (b) (6) MOTHER WENT BACK TO ER, AND THE DOCTOR SAID THAT THE CHILD WOULD BE ADMITTED TO THE HOSPITAL. PEDIATRIC NEUROLOGIST CAME IN AND THEY DID EEG AND CONFIRMED "INFANTILE SPASMS". THIS IS RECOGNIZED UNDER THE EPILEPSY DIAGNOSIS. CHILD IS ON ZANTAC AND ACTHAR (FOR SEIZURES). LAST DOSE OF TEETHING TABLETS WAS 12/04/13. MOTHER HEARD ABOUT THE RECALL THE OTHER DAY AND HAS CONNECTED THE INFANTILE SPASMS WITH THE TEETHING TABLETS. LAST SPASM WAS ON 12/04/13. SHE IS GOING TO TALK TO THE NEUROLOGIST ABOUT THE TEETHING TABLETS. CHILD IS BOTTLE FED. WAS PREMATURE BY 3 – 4 WEEKS. OUR PHARMACIST, EDYTA FRACKIEWICZ, TOLD THE MOTHER THAT IT'S POSSIBLE HER CHILD COULD BE SENSITIVE OR ALLERGIC TO THE TEETHING TABLETS OR SYMPTOMS COULD BE DUE TO SOMETHING ELSE. TOLD HER THAT IF EFFECT IS A TRANSIENT HOMEOPATHIC EFFECT THEN THE SYMPTOMS SHOULD RESOLVE AFTER PRODUCT IS DISCONTINUED. I OFFERED HER A REFUND FOR THE TEETHING TABLETS AND SHE ACCEPTED. PAID $10.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/09/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACIEWICZ

SECTION III: CORRECTIVE ACTION:

12/10/13 (b) (6) PREPARED REFUND REQUEST TOTALING $ 15.79.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6) DATE: 12/10/13

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1521

ADVERSE EVENT SERIOUS: (Y) / N

DSS

ADVERSE EVENT REPORTED ON: 12/09/13 BY: EDYTA FRACKIEWICZ

FEB 05 2014

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 12-17-13

BY: QA / QC DIRECTOR DATE: 12-17-13

cc: QA / QC Production

FEB 04 2014

Individual Case Safety Report

10023432-02-00-07

ANDARD
OPATHIC
HE USA SINCE 1903

Serious Adverse Event
SAE-0056-2013

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot #A97113, are currently in the Standard Homeopathic Co. (SHC) warehouse. All but 7 units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A97113 was manufactured using bulk lot # 120608. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # A97113. The lot was also submitted for microbial testing and all results were within specifications. Additionally, the Baby Teething bulk lot # 120608 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0692-2013) has been received for Hyland's Baby Teething Tablets lot # A97113. Both complaints were reviewed based on the current information available it does not appear that they are related.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A97113.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

12/13/13
Date

DSS
FEB 05 2014

CC-0846-2013
AE-0530-2013
SAE #138
AE #1521
Complaint #2531

FEB 04 2014

Individual Case Safety Report

CaseID: 10023432

10023432-02-00-08

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1521 COMPLAINT #: 2521

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

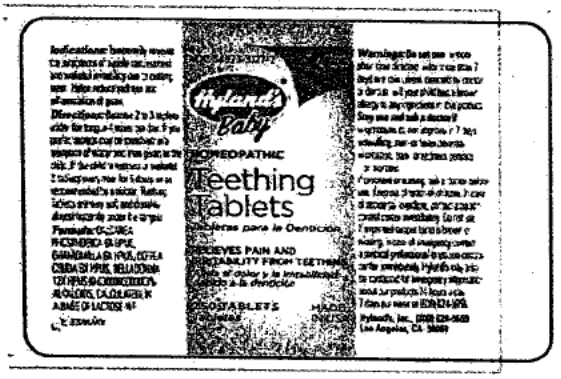
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

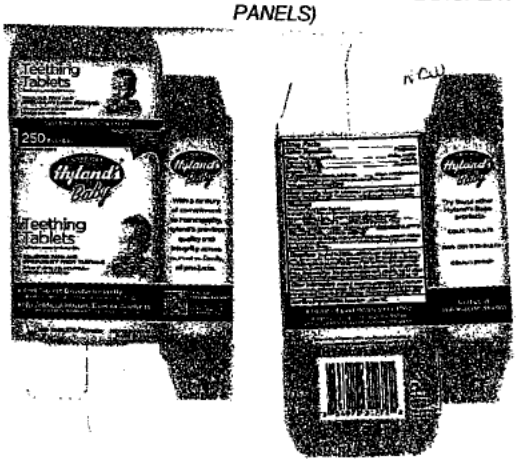
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 12-17-13

DSS

FEB 05 2014

BY: QA / QC DIRECTOR DATE: 12-17-13

DISTRIBUTION: FDA ADVERSE EVENT FILE

FEB 04 2014

FORM SAE01

Individual Case Safety Report

10024252-01-00-01

CaseID: 10024252

Form Approved: OMB No. 0910-0291. Expires 12
See OMB statement on r

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # 54973 P992 2

UF/Importer Report #

FDA Use

FORM FDA 3500A (6/10)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	1 Years or ____ Date of Birth: (b) (6)	☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
01/07/2014	01/16/2014

5. Describe Event or Problem

HAD A SEIZURE ON (b) (6) -- HIS EYES OPENED AND EYES ROLLED UP INTO HIS HEAD AND HE WENT STIFF. LASTED ABOUT 2 MINUTES. WENT TO THE ER AND HAD AN EEG DONE ON (b) (6) (NO RESULTS AVAILABLE).

6. Relevant Tests/Laboratory Data, Including Dates

EEG -- RESULTS PENDING.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give dura from/to (or best estimate)*
#1 2 TABS HS X 1 DOSE	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduce
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☐ No ☑ D A
#2	#2 ☐ Yes ☐ No ☐ D A

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 B06713	#1	#1 ☐ Yes ☐ No ☑ D A
#2	#2	#2 ☐ Yes ☐ No ☐ D A

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Dev
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Profes ☐ Lay User/Pati
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyy*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: JAN 30 2014 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

DS

E. INITIAL REPORTER

1. Name and Address: (b) (6)

Phone # (b) (6)

JAN 29 2014

2. Health Professional?	3. Occupation	4. Initial Reporter Als Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No

FDA USE ONLY

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- [ ] Death
- [ ] Serious Injury
- [ ] Malfunction
- [ ] Other:

2. If Follow-up, What Type?
- [ ] Correction
- [ ] Additional Information
- [ ] Response to FDA Reque
- [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
- [ ] Not Returned to Manufacturer
- [ ] Yes [ ] Evaluation Summary Attached
- [ ] No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
- [ ] Yes [ ] No

6. Evaluation Codes *(Refer to coding manual)*

Method				
Results				
Conclusions				

7. If Remedial Action Initiated, Check Type
- [ ] Recall
- [ ] Repair
- [ ] Replace
- [ ] Relabeling
- [ ] Notification
- [ ] Inspection
- [ ] Patient Monitoring
- [ ] Modification/ Adjustment
- [ ] Other:

8. Usage of Device
- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. [ ] Additional Manufacturer Narrative and / or 11. [ ] Corrected Da

---

1. Check One
- [ ] User Facility
- [ ] Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
- [ ] Initial
- [ ] Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code			
Device Code			

11. Report Sent to FDA?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

12. Location Where Event Occurred
- [ ] Hospital
- [ ] Home
- [ ] Nursing Home
- [ ] Outpatient Treatment Facility
- [ ] Outpatient Diagnostic Facility
- [ ] Ambulatory Surgical Facility
- [ ] Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
- [ ] Foreign
- [ ] Study
- [ ] Literature
- [x] Consumer
- [ ] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
01/10/2014

5.
- (A)NDA # ____
- IND # ____
- STN # ____
- PMA/ 510(k) # ____
- Combination Product [ ] Yes
- Pre-1938 [ ] Yes
- OTC Product [x] Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
- [ ] 5-day
- [ ] 30-day
- [ ] 7-day
- [ ] Periodic
- [ ] 10-day
- [x] Initial
- [x] 15-day
- [ ] Follow-up # ____

8. Adverse Event Term(s)
SEIZURE

9. Manufacturer Report Number
54973 AE # 1525

DSS

JAN 30 2

JAN 29 2014

10024252-01-00-03

OMER COMPLAINT RECORD

CaseID: [illegible]252

COMPLAINT #: 2535

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 01/10/2014

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET—T135

SIZE: 135 TABLETS

LOT NO.: B06713

REPORTER: (b) (6)

ADDRESS:

RECEIVED
JAN 29 2014
CDR

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6) CELL PHONE

E-MAIL:

NATURE OF COMPLAINT: CHILD HAD A SEIZURE ON (b) (6) GAVE BABY TEETHING TABLETS THE NIGHT BEFORE – PUT 2 TABLETS UNDER THE TONGUE. NO VACCINATIONS AROUND THAT TIME. NO FEVER, NO ILLNESS. SEIZURE LOOKED LIKE HIS EYES OPENED AND EYES ROLLED UP INTO HIS HEAD AND HE WENT STIFF. LASTED ABOUT 2 MINUTES. WENT TO THE ER AND FOLLOWED UP WITH SOME TESTS. HAD AN EEG DONE ON (b) (6) BUT NO RESULTS AS OF YET. SEIZURE OCCURRED IN (b) (6) WHERE FAMILY LIVES 6 MONTHS OUT OF THE YEAR. PAID $8 PURCHASED IN (b) (6) WANTS A REFUND. PRESENTLY FAMILY IS LIVING IN (b) (6) TRIED CALLING CUSTOMER ON 01/10/14 FOR US ADDRESS AND LEFT A MESSAGE ON CELL PHONE. TRIED CALLING THREE TIMES ON 01/14/14 BUT THERE WAS NO ANSWER. LEFT ANOTHER MESSAGE. ALSO SENT AN E-MAIL TO CUSTOMER REQUESTING THAT SHE SEND HER U. S. ADDRESS FOR A REFUND.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 01/10/2014

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1525

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 01/10/2014 BY: EDYTA FRACKIEWICZ

DSS
JAN 30

SECTION V:

REVIEWED BY MANAGEMENT BY: DWalk DATE: 01-20-14

BY: Dan Baum QA / QC DIRECTOR DATE: 01-17-14

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

JAN 29 2014

10024252-01-00-04

'STANDARD
HOMEOPATHIC
ADE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0002-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B06713, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B06713 was manufactured using bulk lot # 120917. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B06713. The lot was also submitted for microbial testing and all results were within specifications. Additionally, the Baby Teething bulk lot # 120917 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # B06713. One other SAE (130, lot #B06813) has been reported related to the bulk lot (lot # 120917) used to manufacture the lot indicated in this complaint. Both instances indicate similar reactions. Although two complaints of a similar nature have been received for lots manufactured using bulk lot # 120917 these complaints constitute about a (b) (4) of each lot. We will continue to monitor complaints and if additional complaints are received on this lot or associated bulk lot they will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B06713.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

1/17/14
Date

DSS
JAN 30 2

CC-0026-2014
AE-0012-2014
SAE #141
AE #1525
Complaint #2535

JAN 29 2014

Individual Case Safety Report

10024252-01-00-05

CaseID: 10024252

Hylands®

...OUS ADVERSE EVENT DATA FORM

AE #: 1525 **COMPLAINT #:** 2535

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

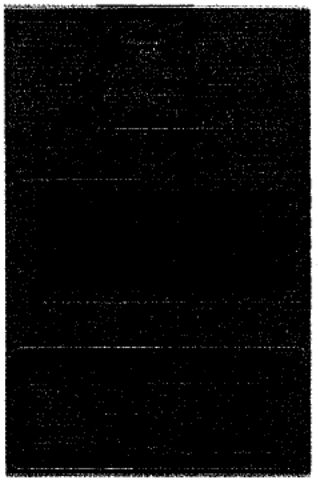
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

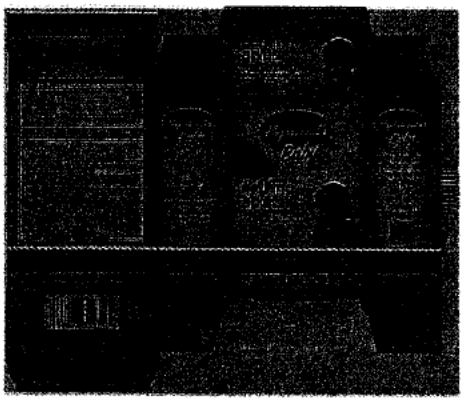
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 01-20-14

BY: Eric Bain DATE: 01-17-14
QA / QC DIRECTOR

DSS JAN 30 20

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JAN 29 2014

Individual Case Safety Report

10027923-01-00-01

CaseID: 10027923

Form Approved: OMB No. 0910-0291, Expires 12/3
See OMB statement on re

For use by user-facilities, distributors and manufacturers MANDATORY reporting

OTC

Mfr Report # 54973 See pg #2

Distributor/Importer Report #

FDA Use

FORM FDA 3500A (6/10)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	15 Months	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
01/28/2014	02/03/2014

5. Describe Event or Problem

SON HAD A SEIZURE AT MIDNIGHT WHEN HE WAS ASLEEP BESIDE HIS MOTHER. IT LASTED 5 MNUTES. HIS EYES ROLLED BACK, AND "IT TOOK A WHILE FOR HIM TO COME OUT OF IT". HE TURNED PURPLE. PARENT CALLED 911 AND AN AMBULANCE BROUGHT HIM TO THE HOSPITAL.

RECEIVED
FEB 25 2014
RECEIVED
FEB 25 2014
CDR

6. Relevant Tests/Laboratory Data, Including Dates

(b) (6) STREP AND FLU TESTS NEGATIVE

CHILD WAS DIAGNOSED AS HAVING HAD A SEIZURE AND WAS SENT HOME TO FOLLOW-UP WITH HIS DOCTOR TODAY.

HOSPITAL GAVE CHILD IBUPROFEN AND PEDIALYTE. HOSPITAL TRIED TO GIVE CHILD AN IV BUT COULDN'T GET A VEIN.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD HAD A LOW GRADE FEVER OF 100.6F. PRIOR TO THE SEIZURE CHILD WAS GIVEN TYLENOL AT 8 PM AND 3 TABLETS OF BABY TEETHING TABLETS AT 10 AM AND AT 5 PM. 24 HOURS PRIOR CHILD HAD BEEN RESTLESS, CRANKY AND CUTTING 3 TEETH. HE HAD BEEN GIVEN TYLENOL FOR THE TEETHING BEFORE WITH NO SYMPTOMS. HIS LAST IMMUNIZATION WAS 3 MONTHS AGO, AND HAE HAD NO REACTION. NO ALLERGIES OR PRE-EXISTING CONDITIONS.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give dura from/to (or best estimate)*
#1 3 TABLETS 2X ON 1/28/14	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☐ No ☑ Do Ap
#2	#2 ☐ Yes ☐ No ☐ Do Ap

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 B26113	#1	#1 ☐ Yes ☐ No ☑ Do Ap
#2	#2	#2 ☐ Yes ☐ No ☐ Do Ap

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

TYLENOL AT 8 PM.

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Dev
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Profes
Serial #	Other #	☐ Lay User/Pati
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

DSS

FEB 26 201

2. Health Professional?	3. Occupation	4. Initial Reporter Als Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No

FEB 25 2014

Individual Case Safety Report

CaseID: 10027923

FDA USE ONLY

10027923-01-00-02

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- [ ] Death
- [ ] Serious Injury
- [ ] Malfunction
- [ ] Other:

2. If Follow-up, What Type?
- [ ] Correction
- [ ] Additional Information
- [ ] Response to FDA Reques
- [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
- [ ] Not Returned to Manufacturer
- [ ] Yes [ ] Evaluation Summary Attached
- [ ] No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
- [ ] Yes [ ] No

6. Evaluation Codes *(Refer to coding manual)*

Method				
Results				
Conclusions				

7. If Remedial Action Initiated, Check Type
- [ ] Recall
- [ ] Repair
- [ ] Replace
- [ ] Relabeling
- [ ] Notification
- [ ] Inspection
- [ ] Patient Monitoring
- [ ] Modification/ Adjustment
- [ ] Other:

8. Usage of Device
- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. [ ] Additional Manufacturer Narrative and / or 11. [ ] Corrected Da

1. Check One
- [ ] User Facility
- [ ] Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
- [ ] Initial
- [ ] Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code			
Device Code			

11. Report Sent to FDA?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

12. Location Where Event Occurred
- [ ] Hospital
- [ ] Home
- [ ] Nursing Home
- [ ] Outpatient Treatment Facility
- [ ] Outpatient Diagnostic Facility
- [ ] Ambulatory Surgical Facility
- [ ] Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

TUTTI GOULD
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
- [ ] Foreign
- [ ] Study
- [ ] Literature
- [x] Consumer
- [ ] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
02/01/2014

5.
- (A)NDA # ____
- IND # ____
- STN # ____
- PMA/ 510(k) # ____
- Combination Product [ ] Yes
- Pre-1938 [ ] Yes
- OTC Product [x] Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
- [ ] 5-day
- [ ] 30-day
- [ ] 7-day
- [ ] Periodic
- [ ] 10-day
- [x] Initial
- [x] 15-day
- [ ] Follow-up # ____

8. Adverse Event Term(s)
FEBRILE SEIZURES

9. Manufacturer Report Number
54973 AE # 1526

DSS
FEB 26 2014

FEB 25 2014

Individual Case Safety Report

10027923-01-00-03

CaseID: 10027923

MER COMPLAINT RECORD

Hyland's

COMPLAINT #: 2536

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 02/01/2014

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABLETS

LOT NO.: B26113

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SON HAD A SEIZURE AT MIDNIGHT WHEN HE WAS ASLEEP BESIDE HIS MOTHER. IT LASTED 5 MINUTES. HIS EYES ROLLED BACK, AND "IT TOOK A WHILE FOR HIM TO COME OUT OF IT". HE TURNED PURPLE. PARENT CALLED 911 AND AN AMBULANCE BROUGHT HIM TO THE HOSPITAL. MEDICAL CARE: HE WAS DIAGNOSED AS HAVING HAD A SEIZURE AND WAS SENT HOME TO FOLLOW-UP WITH HIS DOCTOR TODAY. HE HAD A LOW GRADE FEVER OF 100.6°F. PRIOR TO THE SEIZURE HE WAS GIVEN TYLENOL AT 8 PM AND 3 TABLETS OF BABY TEETHING TABLETS AT 10 AM AND AT 5 PM. AT THE HOSPITAL HE WAS GIVEN IBUPROFEN AND PEDIALYTE. 24 HOURS PRIOR HE HAD BEEN RESTLESS, CRANKY AND CUTTING 3 TEETH. HE HAD BEEN GIVEN TYLENOL FOR THE TEETHING BEFORE WITH NO SYMPTOMS. THE MOTHER SAID THE ONLY THING THAT WAS DIFFERENT WAS SHE GAVE HIM TEETHING TABLETS TWICE THAT DAY. HE HAS NO ALLERGIES OR PRE-EXISTING CONDITIONS. HIS LAST IMMUNIZATION WAS 3 MONTHS AGO, AND HE HAD NO REACTION. AT THE HOSPITAL THEY TRIED TO GIVE HIM AN IV BUT COULDN'T GET A VEIN. BLOOD TESTS FOR STREP AND FLU WERE NEGATIVE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

FOLLOW-UP CALLS: 01/29/14, 01/30/14; LEFT MESSAGE BOTH TIME TO CALL 1-800-624-9659 WITH ANY NEWS FROM THE DOCTOR'S VISIT.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON:** 02/01/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY:** TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1526

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 02/01/2014 BY: TUTTI GOULD

DSS FEB 26

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 02-07-14

BY: Eric Bain QA / QC DIRECTOR DATE: 02-07-14

cc: QA / QC Production

FEB 25 2014

10027923-01-00-04

STANDARD HOMEOPATHIC
BE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0003-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B26113, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B26113 was manufactured using bulk lot # 121648. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B26113. The lot was also submitted for microbial testing and all results were within specifications. Additionally, the Baby Teething bulk lot # 121648 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # B26113. One other complaint (CC-0886-2013, lot # B25913) has been reported related to the bulk lot (lot # 121648) used to manufacture the lot indicated in this complaint. Both complaints were reviewed and they were not similar. We will continue to monitor complaints and if additional complaints are received on this lot or associated bulk lot they will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B26113.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

02/07/2014
Date

DSS
FEB 26 20

SAE 143
AE #1526
Complaint #2536
CC-0066-2014
AE-0029-2014

FEB 25 2014

Individual Case Safety Report

10027923-01-00-05

CaseID: 10027923

Hyland's®

...JUS ADVERSE EVENT DATA FORM

AE #: 1526 **COMPLAINT #:** 2536

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 02-07-14 DSS

BY: QA / QC DIRECTOR DATE: 02-07-14

FEB 26 201

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

FEB 25 2014

Individual Case Safety Report

CDER

CaseID: 10040722

10040722-01-00-01

umer Report

RY reporting of
luct problems and
product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 544661

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	0 (b) (6)	☑ Female ☐ Male	17 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/25/2014	03/25/2014

5. **Describe Event, Problem or Product Use Error**
My baby spits up or vomits after consuming Hyland Teething Tablets.

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
Race:White

Medical Conditions:

Allergies:

Important Information:

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
#1 Name: Hylands Teething Tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 pills	once	Taken by mouth
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 03/22/2014 - 03/25/2014
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 Teething pain
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

CTU
MAR 26 2014

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	**Other #**	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
Name: (b) (6)
Address:
City: State: -- ZIP:

DSS
MAR 26

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

10149861-01-00-01

...DER
...umer Report
...RY reporting of
...duct problems and
product use errors

CaseID: 10149861

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	548761

1/2

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	2 Years (b) (6)	☐ Female ☑ Male	_____ lb or _____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	04/30/2014

5. Describe Event, Problem or Product Use Error

My son did not get his first tooth until almost after a year old. A friend of mine told me about hylands because I do NOT just give my child medication . I thought it was natural and safe. I used it as needed occasionally over a corse of maybe 5 months. Out of the clear blue I noticed my son staring off and his eye twitching. At first my boyfriend thought he was in deep thought and my mother did too. I'm with my son every day and I rarely miss a thing. Over a corse of a few days they came more often. The ONLY thing I ever gave my son was hylands teething tablets. He had an EEG and which came ...

6. Relevant Tests/Laboratory Data, Including Dates

EEG positive for seizures.MRI within Norman limits

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:White

Medical Conditions: None

Allergies: None

Important Information:

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Name: Teething tablets
Strength: Hylands
Manufacturer: OTC

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

MAY - 1 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS

MAY 01 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

... back positive for seizures. Which I supspected . We just had an MRI done and it came back clear . There is absolutely NO doubt that this is from hylands teething tablets. I immediately stopped using them. But the damage has been done. My son is senitive to a lot of things, and I believed he was poisoned by these without me knowing.

Individual Case Safety Report

10149861-01-00-02

Individual Case Safety Report

10162192-01-00-01

CDER

fessional Report

Case ID: 10162192

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

.Y reporting of
.uct problems and
product use errors

1/1

The FDA Safety Information and
Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 549451

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	1 Years (b) (6)	☑ Female ☐ Male	19.9 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/26/2013	05/07/2014

5. Describe Event, Problem or Product Use Error
Single seizure: brief staring episode at home, appearing awake but unresponsive that lasted seconds, and then "seemed more out of it than usual". No report of loc. No tonic/clonic shaking. vomited after event. fatigued for an hour after event. took Hyland's teething tablets prior to event. After event tablets stopped- has not had another seizure like episode since.

6. Relevant Tests/Laboratory Data, Including Dates
EEG nl, cbc/ lytes normal

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
previously healthy, no preexisting conditions.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hyland's teething tablets
Strength:
Manufacturer: Hyland's

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 as directed	PRN/as needed	Oral
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 09/19/2013 - 09/26/2013
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

MAY - 8 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*
none

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS

MAY 08 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Medical Doctor (Physician)	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Case Safety Report

10162223-01-00-01

CDER

ofessional Report

RY reporting of
duct problems and
product use errors

CaseID: 10162223

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 549447

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	7 Months (b) (6)	☑ Female ☐ Male	17.5 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/25/2013	05/07/2014

5. Describe Event, Problem or Product Use Error
3 episodes of seizure activity involving arms/ legs, all occurring on the same day. Hospitalized for 24hrs. For the 5 days prior to seizure, patient had started taking Hyland's teething tablets. This was discontinued on the day of admission. The patient's EEG, MRI were all normal. There was no family history of seizures or any history of febrile seizures. She has not had any seizures or Hyland's teething tablets since this time.

6. Relevant Tests/Laboratory Data, Including Dates
EEG normal: (b) (6) Brain MRI (b) (6) normal,

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
prior 38 week twin, other twin unaffected. no preexisting health issues, no family history of seizures or neurologic problems

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hyland's Teething Tablets
Strength: unsure
Manufacturer: Hyland

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 as directed on label	PRN/as needed	Oral
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/20/2013 - 10/25/2013
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name
CTU

3. Manufacturer Name, City and State
MAY - 8 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
MAY 08 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Medical Doctor (Physician)	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

10234825-01-00-01

OTC

...y use facilities, ...utors and manufacturers ...ATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

RECEIVED JUN 10 2014 CDR

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event: 14 Months or Date of Birth:
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: ____ (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 05/21/2014

4. Date of This Report (mm/dd/yyyy): 05/23/2014

5. Describe Event or Problem

CHILD WITH ALTERED MENTAL STATUS DESCRIBED AS CLUMSINESS, FALLING DOWN, IRRITABILITY, SOMNOLENCE.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

CT SCAN, MRI, LABS, X-RAYS WERE NORMAL.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2-3 TABS QID ... MONTH
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-2

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Unique Identifier (UDI) #

5. Operator of Device
- ☐ Health Professional
- ☐ Lay User/Patient
- ☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
JUN 11 2014

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

JUN 10 2014

Phone # (b) (6)

Email Address

2. Health Professional? ☑ Yes ☐ No

3. Occupation: Physician

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☑ No ☐ Unk.

CaseID: 10234825

Individual Case Safety Report

10234825-01-00-02

FDA USE ONLY

5

1. Check One
☐ User Facility ☐ Importer

2. If Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code _____ – _____ – _____
Device Code _____ – _____ – _____

11. Report Sent to FDA?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
EDYTA FRACKIEWICZ
Address
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address
STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☑ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
05/21/2014

5.
(A)NDA # _____
IND # _____
BLA # _____
PMA/ 510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
ALTERED MENTAL STATUS

9. Manufacturer Report Number
54973 AE # 1537

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: _____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code _____ – _____ – _____
Device Code _____ – _____ – _____
Method _____ – _____ – _____ – _____
Results _____ – _____ – _____ – _____
Conclusions _____ – _____ – _____ – _____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other: _____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUN 11 2014

JUN 10 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report

ECORD

ID: 10234825

10234825-01-00-03

COMPLAINT #: 2547

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/21/2014

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: DID NOT HAVE BOTTLE

LOT NO.: DID NOT HAVE BOTTLE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT: MOM HAS BEEN GIVING HYLAND'S BABY TEETHING TABLETS POSSIBLE UP TO 2 – 3 TABS FOUR TIMES A DAY FOR 1 MONTH. CHILD PRESENTS WITH ALTERED MENTAL STATUS DESCRIBED AS CLUMSINESS, FALLING DOWN, IRRITABILITY, SOMNOLENCE. HOSPITALIZED. SEROQUEL ALSO PRESENT IN THE HOME. DOCTOR REQUESTED MORE INFORMATION ABOUT HYLAND'S BABY TEETHING TABLETS. CT SCAN, MRI, LABS, X-RAY NORMAL. TOLD HIM THAT I WOULD FILE A REPORT WITH THE FDA SINCE CHILD HOSPITALIZED. TOLD PHYSICIAN THAT CUSTOMER USING PRODUCT FOR LONGER THAN RECOMMENDED DURATION COULD CAUSE A HOMEOPATHIC EFFECT, OR CHILD COULD BE SENSITIVE OR ALLERGIC TO AN ACTIVE OR INACTIVE INGREDIENT, OR SYMPTOMS COULD BE DUE TO SOMETHING ELSE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 05/21/2014

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

JUN 11 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1537

ADVERSE EVENT SERIOUS: (Y) / N

JUN 10 2014

ADVERSE EVENT REPORTED ON: 05/21/2014 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 06-02-14

BY: Eric Braun 06-02-14 DATE: 06-02-14

QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

Individual Case Safety Report

10234825-01-00-04

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erse Event

SAE-0014-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible.

The customer complaint system was reviewed and it did reveal that in the last twelve months that there have been seventy-two Adverse Event (AE) which also included eleven Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum was "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

5/29/14
Date

DSS
JUN 11 2014

JUN 10 2014

CC-0316-2014
AE-0166-2014
CC # 2547
AE # 1537

CaseID: 10234825

Individual Case Safety Report

10234825-01-00-05

DATA FORM

AE #: 1537 COMPLAINT #: 2547

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: UNKNOWN

ADDRESS:

CITY: STATE: (b) (6)

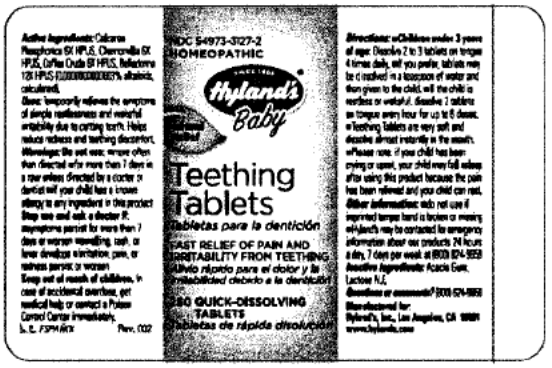
COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

DSS
JUN 11 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

JUN 10 2014

REVIEWED BY MANAGEMENT BY: R Wolf DATE: 06-02-14

BY: Eric Bain DATE: 06-02-14
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE **FORM SAE01**

CaseID: 10234831

Individual Case Safety Report

10234831-01-00-01

OTC

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rs and manufacturers
ORY reporting

of 5

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event: 10 Months or Date of Birth:
3. Sex: [x] Female [ ] Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death: ____ (mm/dd/yyyy)
- [ ] Disability or Permanent Damage
- [ ] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [x] Hospitalization - initial or prolonged
- [ ] Other Serious (Important Medical Events)
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 04/30/2014 05/11-12/2014

4. Date of This Report (mm/dd/yyyy): 05/16/2014

5. Describe Event or Problem

CHILD HAD 1 OR 2 DOSES RANDOMLY OF TEETHING TABLETS. MAYBE 4 TABS A DAY A FEW WEEKS AGO. SHE WAS FINE FOR A COUPLE WEEKS THEN SHE STARTED TO DO THIS WEIRD THING AND TURNED BLUE. TOOK HER TO THE ER AND SHE WAS MIS-DIAGNOSED ON (b) (6) WITH PNEUMONIA. THE EVENTS WHERE SHE STOPPED BREATHING AND TURNED BLUE KEPT HAPPENING AGAIN ON MOTHER'S DAY. (b) (6) THEY WENT TO THE HOSPITAL. THEY HOOKED HER UP TO A MACHINE AND SAW SHE WAS HAVING 20 OR MORE SEIZURES IN 1 DAY. HER MRI WAS CLEAR. THEY KEPT HER OVERNIGHT AND SHE IS NOW TAKING KEPPRA. SHE HAD NOT TAKEN ANY TEETHING TABLETS FOR A COUPLE WEEKS BEFORE SHE HAD THE SEIZURE. MOTHER READ ON INTERNET ABOUT RECALL AND WAS CONCERNED.

RECEIVED
JUN 10 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(b) (6) MRI WAS CLEAR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2 TABLETS AS NEEDED
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [x] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1 113749
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [x] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID
54973-3127-2

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Unique Identifier (UDI) #

5. Operator of Device
- [ ] Health Professional
- [ ] Lay User/Patient
- [ ] Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
JUN 11 2014

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

JUN 10 2014

Phone # (b) (6)

Email Address

2. Health Professional? [ ] Yes [x] No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA? [ ] Yes [ ] No [x] Unk.

CaseID: 10234831

Individual Case Safety Report

10234831-01-00-02

FDA USE ONLY

5

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___

11. Report Sent to FDA?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: ALISON MC PEAK
Address:
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: alison.mcpeak@homeopathiclaboratories.c

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*

5.
(A)NDA # _____
IND # _____
BLA # _____
PMA/ 510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ___

9. Manufacturer Report Number
54973 AE # 1536

8. Adverse Event Term(s)
SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other: _____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS
JUN 11 2014

JUN 10 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report

10234831-01-00-03

T RECORD

ID# 10234831

COMPLAINT #: 2546

TAKEN BY: ALISON MC PEAK

DATE OF COMPLAINT: 05/15/2014

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T250

SIZE: 250 TABLETS

LOT NO.: 113749

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CHILD HAD 1 OR 2 DOSES RANDOMLY OF TEETHING TABLETS. MAYBE 4 TABLETS A DAY A FEW WEEKS AGO. SHE WAS FINE FOR A COUPLE WEEKS THEN SHE STARTED TO DO THIS WEIRD THING AND TURNED BLUE. TOOK HER TO THE ER AND SHE WAS MIS-DIAGNOSED ON (b) (6) WITH PNEUMONIA. THE EVENTS WHERE SHE STOPPED BREATHING AND TURNED BLUE KEPT HAPPENING AGAIN ON MOTHER'S DAY. MONDAY, (b) (6) THEY WENT TO THE HOSPITAL. THEY HOOKED HER UP TO A MACHINE AND SAW SHE WAS HAVING 20 OR MORE SEIZURES IN 1 DAY. HER MRI WAS CLEAR. THEY KEPT HER OVERNIGHT AND SHE IS NOW TAKING KEPPRA. SHE HAD NOT TAKEN ANY TEETHING TABLETS FOR A COUPLE WEEKS BEFORE SHE HAD THE SEIZURE. MOTHER READ ON INTERNET ABOUT RECALL AND WAS CONCERNED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

05/15/14 AMP: HER BOTTLE OF TEETHING TABLETS WERE NOT PART OF RECALL.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/15/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: ALISON MC PEAK

SECTION III: CORRECTIVE ACTION:

DSS

CORRECTIVE ACTION(S) COMPLETED BY: DATE: JUN 11 2014

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1536

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/15/14 BY: ALISON MC PEAK

SECTION V:

JUN 10 2014

REVIEWED BY MANAGEMENT BY: DATE: 05-28-14

BY: QA / QC DIRECTOR DATE: 05-27-14

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

Individual Case Safety Report

10234831-01-00-04

...e Event

SAE-0013-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # 113749, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b)(4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # 113749 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # 113749. The lot was also submitted for microbial testing and all results were within specifications. Additionally, the Baby Teething bulk lot # 113749 was tested for total Atropine and Scopolamine and the results were with in specification of ≤ (b)(4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # 113749. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # 113749.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

5/23/14
Date

DSS
JUN 11 2014

JUN 10 2014

CC-0307-2014
AE-0163-2014

CaseID: 10234831

Individual Case Safety Report

10234831-01-00-05

Hyland's®

VENT DATA FORM

AE #: 1536 **COMPLAINT #:** 2546

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

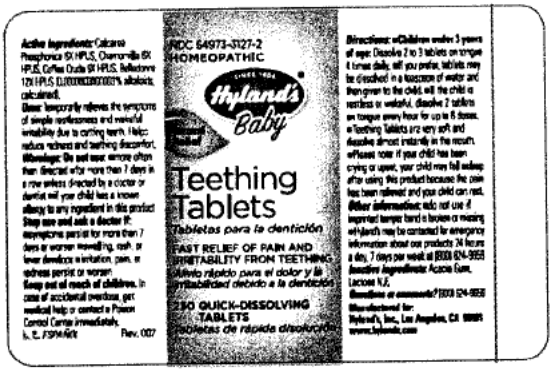
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

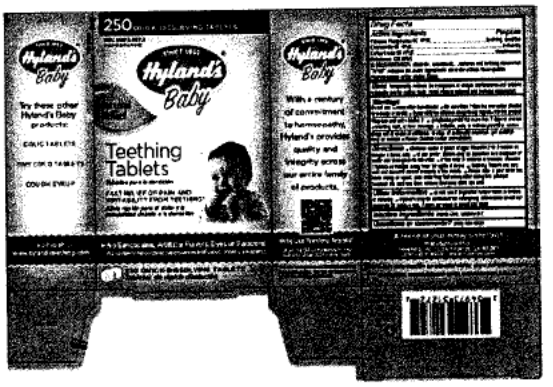
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS
JUN 11 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

JUN 10 2014

REVIEWED BY MANAGEMENT BY: DATE: 05-28-14

BY: DATE: 05-27-14

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 10257359

1/3

10257359-01-00-01

MedWatch — OTC

The FDA Safety Information and Adverse Event Reporting Program

...RY reporting of ...duct problems and product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 554682

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	9 Months (b) (6)	☐ Female ☑ Male	21 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
05/21/2014	06/22/2014

5. Describe Event, Problem or Product Use Error

I started giving my son hylands teething tablets, 2 pills at a time up to 4 dose's daily never more than twice in a hour. He started "Jerking" and I thought it was add excitement jerks or something. one day he started doing it a lot more than ever before so I took him to (b) (6) hospital er and got him checked out. They say it was the form of a seizure but that it was not because he was still focusing her was just "jerking" taking his head to his shoulder and locking up his muscles for 2-7 sec. So we went home he continues to jerk for a week longer as I am still giving him the ...

6. Relevant Tests/Laboratory Data, Including Dates

none.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:White

For additional information see B7 below.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Name: Hylands teething tablet
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 to 3 tablets	Four times daily	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 03/10/2014 - 05/20/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething - I was told it worked better than oral gel's
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
54973-3127-3

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU
JUN 23 2014

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

DSS
JUN 23 2014

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

... teething tablets for teething and then I came across a recall for his tablets. I then made a apt with his dr at (b) (6) which tells me the teething tablets have belladonna and that it causes toxicity and to immediately quit giving these tablets to my son. So I threw away all 3 box's I had and even took and threw away the ones at his daycare I gave them. With in 1 week of not having any teething tablets my son has quit "jerking" and is acting completely normal again.

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Medical Conditions: none

Allergies: none

Important Information: none

RX Meds: none

OTC Meds: none

Individual Case Safety Report

10267562-01-00-01

CaseID: 10267562

OTC

...by user-facilities, ...ibutors and manufacturers
...DATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report # 54973 See 2nd page

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (2/13)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	18 Months	☑ Female ☐ Male	____ lbs or ____ kgs
In confidence	or Date of Birth:		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: _____ (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
09/01/2013 -- 06/06/2014	06/12/2014

5. Describe Event or Problem

CHILD EXPERIENCING SEIZURE ACTIVITY AND DELAYS IN SPEECH FOR THE PAST 9 MONTHS. SEIZURES DESCRIBED AS CHILD HOLDING HER BREATH, PASSING OUT, LEGS WILL START SHAKING, AND SHE WILL BITE DOWN.

RECEIVED
JUN 24 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

ALLERGIC TO MILK, EGGS, PEANUTS

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 4 TABS QD PRN X 9 MOS	#1
#2	#2

4. Diagnosis for Use (Indication)	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
JUN 25 2014

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)
MD

USA
JUN 24 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

Individual Case Safety Report

CaseID: 10267562

10267562-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)* ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/06/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURES, SPEECH DELAY
9. Manufacturer Report Number: 54973 AE # 1542

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUN 25 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
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10267562-01-00-03

OMPLAINT RECORD

ID 10267562

1830 0004 8628 8627

COMPLAINT #: 2552

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/06/14

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: THREW BOTTLE AWAY

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: VOICE MAIL MESSAGE: MOTHER CALLED REGARDING DAUGHTER STATING IN VOICE MAIL MESSAGE THAT SHE RECENTLY STARTED HAVING SEIZURE ACTIVITY. DOCTOR TOLD HER TO NOT TO USE BABY TEETHING TABLETS AND SHE HAS USED PRODUCT FOR 6 – 8 MONTHS. SPOKE WITH MOTHER 06/11/14: MOTHER RECENTLY NOTICED SOME SPEECH DELAY WHICH SHE ATTRIBUTES TO THE HYLAND'S TEETHING TABLETS BECAUSE SEIZURE ACTIVITY SLOWS THE BRAIN ACTIVITY AND CAUSES DELAYS IN SPEECH. THREW BABY TEETHING TABLETS AWAY ON FRIDAY 06/06/14. WAS GIVING CHILD 4 TABLETS EVERY DAY FOR 9 MONTHS WHEN HER TEETH HURT. DESCRIBES SEIZURES AS CHILD HOLDING HER BREATH, PASSING OUT, LEGS WILL START SHAKING AND SHE WILL BITE DOWN. SEIZURES GOING ON SINCE SHE WAS 9 MONTHS OLD SO FOR ABOUT 9 MONTHS. DOCTOR SAID THAT TEETHING TABLETS WERE CAUSING THE SEIZURES. NO TESTS FOR SEIZURES ADMINISTERED BY DOCTOR AT THIS TIME. MOTHER STOPPED THE TABLETS ON FRIDAY. CHILD HAS THE SEIZURES ONCE A DAY, BUT STOPPED HAVING THEM FRIDAY AFTERNOON AFTER DISCONTINUING TEETHING TABLETS. CUSTOMER DID NOT REQUEST A REFUND OR REPLACEMENT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 06/06/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY: DATE: JUN 25 2014

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1542

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/06/14 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalff DATE: 06-17-14

BY: Dyman Daub QA / QC DIRECTOR DATE: 06-16-14

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

STANDARD OPATHIC
IE USA SINCE 1903

Serious Adverse Event
SAE-0019-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been sixty-three Adverse Events (AE) which also included nine Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tables. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

6/17/14
Date

DSS
JUN 25 2014

Complaint 2552
AE# 1542
SAE# 159
CC-0379-2014
AE-0205-2014

Individual Case Safety Report

CaseID: 10267562

10267562-01-00-05

EVENT DATA FORM

AE #: 1542 **COMPLAINT #:** 2552

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

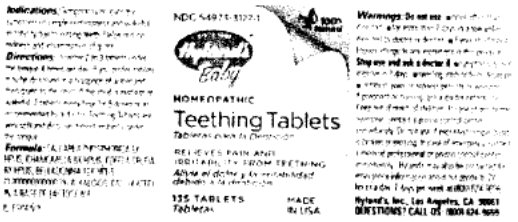
COUNTRY: USA ZIP CODE:

PHONE #:

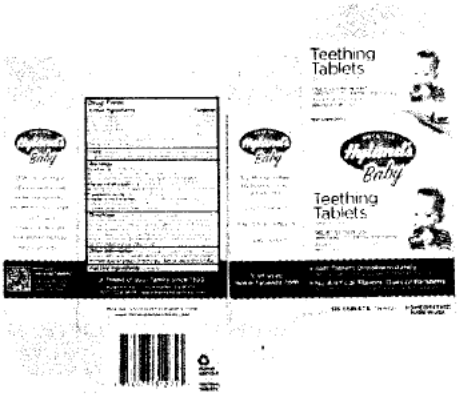
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS

JUN 25 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-17-14

BY: QA / QC DIRECTOR DATE: 06-16-14

DISTRIBUTION: FDA ADVERSE EVENT FILE **FORM SAE01**

Individual Case Safety Report

CaseID: 10272692

10272692-01-00-01

...ner Report CDER

...Y reporting of ...ict problems and ...product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 555559

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	18 Months (b) (6)	☑ Female ☐ Male	25 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/24/2014	06/27/2014

5. Describe Event, Problem or Product Use Error

My 18 month old daughter has been using the hylands teething tablets for 3 weeks now. In the last two weeks she has had a horrible rash appearing as similar to the looks of ring worm, but all over her body it would stay for 12-24 hours then disappear for a day or two. When this rash would pop up I needed to have her use her nebulizer to help with her breathing. I brought her to the doctors yesterday 06/26/14. They have referred her to an allergist hoping to maybe find out what causes it, that appointment is 07/21/14.

6. Relevant Tests/Laboratory Data, Including Dates

My 18 month old ...

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:White

For additional information see B7 below.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hylands Teething Tablets
Strength:
Manufacturer: Hylands Inc.

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2-3 tablets	Four times daily	Taken under the tongue
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 06/05/2014 - 06/23/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething child with sore gumbs.
#2

6. Lot #	7. Expiration Date
#1 B32713	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

JUN 30 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
JUN 30 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

... daughter will have to undergo a 2 1/2 -3 hour allergy test to try and help figure out the problem.

Individual Case Safety Report

10272692-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Medical Conditions: Asthma

Allergies: N/A

Important Information: N/A

RX Meds: N/A

OTC Meds: N/A

Individual Case Safety Report

10272692-01-00-03

Individual Case Safety Report

10272885-01-00-01

CaseID: 10272885

CDER DQRS 07/6

sumer Report

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

RY reporting of
duct problems and
product use errors

1/2

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 555606

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6)	7 Months (b) (6)	☐ Female ☑ Male	20 lb or ____ kg

In confidence

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)*
☐ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
12/24/2012	06/28/2014

5. Describe Event, Problem or Product Use Error

Hello, my name is (b) (6) My son was taking the Hylands Teething Tablets in Oct 2012 I don't know there was a recall on them. In (b) (6) my son started having seizures back to back for no reason they thought it was from fever but it was most of the time there was no fever n he's on keppa twice a day for the seizures and the doctor still doesn't know or can't find a link to why he are having them . He also has a speech delay he was doing fine with his speech until he started having the seizures. He currently is taking medicine for seizures twice a day n going to speech twice a ...

6. Relevant Tests/Laboratory Data, Including Dates

EKG, (b) (6)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:Black/African American

For additional information see B7 below.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Name: Hylands
Strength: Teething Tablets
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/01/2012 - 01/16/2013
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething purposes
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU
JUN 30 2014

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
JUN 30 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

... week. I need some answers I also recently gave my 9 month old the same tablets n he have been to the er for having seizures lucky I stopped the tablets and he haven't had another one. Can you please contact me ASAP I have a case that needs to be claimed thank you for your time I look forward to hearing from someone soon. (b) (6) or (b) (6)

Individual Case Safety Report

10272885-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Medical Conditions: Seizures and speech delay

Allergies: Pollen

Important Information: None

RX Meds: Keppra 3.0 twice a day

OTC Meds: None

CaseID: 10275530

10275530-01-00-01

CDER

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product use errors

1/3

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 555545

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	1 Years (b) (6)	☑ Female ☐ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/07/2014	06/27/2014

5. Describe Event, Problem or Product Use Error
My 14 mon. old daughter was taking hyland teething tablets... she had a seizure, has had breathing problems and extremely fatigue! I'm curious if this will cause long time effects and what can be done?

6. Relevant Tests/Laboratory Data, Including Dates
My doctor has ...

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
Race: White

For additional information see B7 below.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: teething tablets and teething ge
Strength: hylands teething tablets and gel
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 09/01/2013 - 06/18/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Cutting teeth and pain. I used to avoid pain meds.
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU

2. Common Device Name

JUN 30 2014

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
JUN 30 2014

Phone #	E-mail
(b) (6)	

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

5555475

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

... records of the fatigue and breathing problems and she was taking by ambulance to the ER for a siezure just recently.

Individual Case Safety Report

10275530-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Medical Conditions:

Allergies:

Important Information:

RX Meds: Amoxicillan antibiotic for ear infection

OTC Meds: Tylenol. clartin. orajel.

Individual Case Safety Report

10275530-01-00-03

REPORT INFORMATION

1/7

CDER

177283
OTC

Report Profile

Report Version	FPSR.FDA.DSR.V.V1
Report Category	Voluntary Dietary Supplements Report
Submitted	2014-06-20 01:06:26 EST
FDA ICSR ID	1035209
Report Key for Followup	38BEF829-163F02F2-AEBE2280-8829111D-98858ECF-8329673E-2A8FAC1B-46A682C1

Report Identifying Information

CTU

JUL - 3 2014

Please enter a title to help you identify this report.	Hyland's Teething Tablets
What type of report are you submitting?	Adverse event (an adverse health-related event associated with the product)
Regulatory Status	Voluntary

CAERS 06/20/2014

DSS

JUL 03 2014

10283615-01-00-02

Contact Information- Your Contact Information

Do you wish to remain anonymous to the FDA?	No
First name	(b) (6)
Last name	
Email	
Confirm email	
Phone	
Country	United States
Street adddress line 1	(b) (6)
Street address line 2	<blank>
City/Town	(b) (6)
State	
Mail/ZIP code	
Have you reported the event to any of the following?	<blank>
Are you a healthcare professional?	No

Relevant Details

Patient/Consumer identifier	(b) (6)
Gender	Male
Age at time of event, if unknown, please enter Date of birth below	2
Select unit of measure	Month(s)
Date of birth	(b) (6)
Weight	13
Select unit of measure	Pound(s)
Height	25
Select unit of measure	Inch(inches)

Problem Details

Outcomes attributed to adverse event (check all that apply)	Other

If other, please describe	symptoms like spasms
Please describe the event or problem	After I gave my son Hyland's Teething Tablets, either his legs, arms or body would look like he was having spasms. After I saw a post on Facebook, I did some research. I am taking my son to his pediatrician first thing tomorrow morning.
Date of event	04/22/2014
Duration of adverse event	2
Select unit of measure	minute
Please provide relevant medical history, including pre-existing conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) :	N/A
Do you have any relevant tests/laboratory data information to report?	No

Individual Case Safety Report

10283615-01-00-03

Adverse Event Terms

Adverse event term	Hyland's Teething Tablets
If other, please describe	Hyland's Teething Tablets

Relevant Tests/Laboratory Data

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Homeopathic Hyland's Baby Teething Tablets
Product manufacturer, packer, distributor	Hyland's,Inc.
Product strength	<blank>
Select unit of measure	<blank>
Barcode identifier	<blank>
Select identifier type	<blank>
If other, please describe	<blank>
Diagnosis or reason for use (indication):	Relief due to teething.
Lot number	A24314
Expiration/use-by date	06/30/2014
Is the product available for evaluation by the FDA?	Unknown

DSS

JUL 03 2014

Was product returned to manufacturer? No

556115

Individual Case Safety Report

10283615-01-00-04

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	04/22/2014
End:	06/19/2014
Duration of product use	2
Select unit of measure	month(s)
Frequency of consumption	<blank>
Select unit of measure	<blank>
Amount consumed per serving	<blank>
Select unit of measure	<blank>
Administration route	<blank>

Relatedness Details

Did the event stop when product use stopped or amount consumed was reduced?	Yes
Did the event reoccur when product use resumed?	Not Applicable
Please provide any notes describing the product's usage.	<blank>

Ingredient Details

Ingredient name	Belladonna 12X HPUS
If other, please describe	Belladonna 12X HPUS
Ingredient amount	<blank>
Select unit of measure	<blank>

DSS

JUL 03 2014

Ingredient Details

Ingredient name	Calcarea Phosophorica 6X HPUS
If other, please describe	Calcarea Phosophorica 6X HPUS

Ingredient Details

Ingredient name Chamomilla 6X HPUS

If other, please describe Chamomilla 6X HPUS

Ingredient amount <blank>

Select unit of measure <blank>

Ingredient Details

Ingredient name Coffea Cruda 6X HPUS

If other, please describe Coffea Cruda 6X HPUS

Ingredient amount <blank>

Select unit of measure <blank>

Ingredient Details

Ingredient name Arcacia Gum

If other, please describe Arcacia Gum

Ingredient amount <blank>

Select unit of measure <blank>

Ingredient Details

Ingredient name Lactose N.F.

If other, please describe Lactose N.F.

Ingredient amount <blank>

Select unit of measure <blank>

Product Relevant Details

I have reviewed the ingredients listed for

each product, if available, and made any necessary corrections Yes

Individual Case Safety Report

10283615-01-00-06

Concomitant Product Information

Concomitant Product Relevant Details

HL7 Batch Information

HL7 Batch Control Information

Submitting Organization Id (b) (6)

HL7 Batch Sender Information

Sender Id GuestAccount

HL7 Batch Receiver Information

Batch Receiver (Root) USFDA

Batch Receiver (Extension) US Food and Drug Administration

DSS

JUL 03 2014

HL7 Message Information

HL7 Message Control Information

Unique Sender Identifier (b) (6)

000006

HL7 Message Sender Information

Unique Sender Identifier ID-NOTGIVEN

Organization Name UNKNOWN

Title Voluntary Dietary Supplement Submitter

HL7 Message Receiver Information

Message Receiver Id USFDA

Attached Files

FILENAME 100_1327.JPG

Description of Attachment Bottle of Homeopathic Hyland's Baby Teething Tablets.

Attachment Type Labeling Materials

FILENAME 100_1326.JPG

Description of Attachment Bottle of Homeopathic Hyland's Baby Teething Tablets.

Attachment Type Labeling Materials

FILENAME 100_1324.JPG

Description of Attachment Bottle of Homeopathic Hyland's Baby Teething Tablets.

Attachment Type Labeling Materials

Individual Case Safety Report

10285322-01-00-01

CaseID: 10285322

OTC

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

user-facilities,
tors and manufacturers
TORY reporting

Mfr Report # 54973 Page 2

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	1.5 Years	☑ Female ☐ Male	lbs or kgs
In confidence	or Date of Birth:		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
08/00/2013	06/23/2014

5. Describe Event or Problem

FATHER CALLED WONDERING IF HIS 2 YEAR OLD DAUGHTER'S SEIZURE FROM A YEAR AGO COULD HAVE BEEN CAUSED BY BABY TEETHING TABLETS. SHE WENT TO THE HOSPITAL AND ALL TESTS WERE NORMAL. DOCTOR COULD NOT DETERMINE CAUSE. JUST PRIOR TO SEIZURE CHILD WAS PLAYING IN THE WATER THE DAY, AND WAS CRYING. FATHER SAID THEY CONSIDERED WHTHER SHE HAD "DROWNED AND COME BACK" FROM TOO MUCH WATER. EMT'S RULED OUT HOSE INCIDENT AS POSSIBLE CAUSE OF SEIZURE.

SEIZURE SYMPTOMS: LEFT ARM AND BODY SHAKING, SOME FOAM FROM MOUTH, ALWAYS ABLE TO BREATHE, EYES GLAZED, STARING, UNRESPONSIVE TO HER NAME, LASTED 1 MINUTE.

CHILD CONTINUED TO TAKE THE REMEDY UNTIL PRESENT (1 YEAR PRIOR TO, AND FOR A YEAR AFTER THE SIEZURE). THERE WAS ONLY ONE INCIDENT OF THE SEIZURE.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

TESTS DONE AND REPEATED EVERY MONTH FOR 6 MONTHS: BRAIN EEG, BRAIN SCAN, BLOOD WORK, HEART TESTS.

SPECIALIST: NEUROLOGY

ALL TESTS WERE NORMAL.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

JUST PRIOR TO SEIZURE CHILD WAS PLAYING IN THE WATER WITH A HOSE, AND WAS CRYING. FATHER SAID THEY CONSIDERED WHETHER SHE HAD "DROWNED AND COME BACK" FROM TOO MUCH WATER. EMT'S RULED OUT HOSE INCIDENT AS POSSIBLE CAUSE OF SEIZURE.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1-2 TABS Q4H	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP [illegible] TEETHING PAIN

#2

RECEIVED

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	JUL 02 2014
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID CDR

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

TYLENOL

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: *(mm/dd/yyyy)* JUL 08 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

JUL 02 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

Individual Case Safety Report

10285322-01-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)* | **7. Type of Report** ☐ Initial ☐ Follow-up # ____ | **8. Date of This Report** *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

11. Report Sent to FDA?

☐ Yes ____ *(mm/dd/yyyy)*

☐ No

12. Location Where Event Occurred

☐ Hospital ☐ Outpatient Diagnostic Facility

☐ Home ☐ Ambulatory Surgical Facility

☐ Nursing Home

☐ Outpatient Treatment Facility

☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?

☐ Yes ____ *(mm/dd/yyyy)*

☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address:
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*

☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/20/2014

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*

☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number: 54973 AE # 1544

8. Adverse Event Term(s): SEIZURE

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event

☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?

☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?

☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type

☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device

☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS
JUL 03 2014

JUL 02 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

10285322

SECTION I: **COMPLAINT**

COMPLAINT #: 2554

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 06/20/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: NOT AVAILABLE

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: FATHER CALLED WONDERING IF HIS 2 YEAR OLD DAUGHTER'S SEIZURE FROM A YEAR AGO COULD HAVE BEEN CAUSED BY BABY TEETHING TABLETS. SHE WENT TO THE HOSPITAL AND ALL TESTS WERE NORMAL. DOCTOR COULD NOT DETERMINE CAUSE. CHILD WAS IMMUNIZED 6 MONTHS PRIOR, HAD TAKEN TYLENOL THE NIGHT BEFORE. JUST PRIOR TO THE SEIZURE SHE HAD BEEN PLAYING IN THE WATER WITH HOSE, AND WAS CRYING, FATHER SAID THEY CONSIDERED WHETHER SHE MAY HAVE "DROWNED AND COME BACK" FROM TOO MUCH WATER. SEIZURE SYMPTOMS: LEFT ARM AND BODY SHAKING, SOME FOAM FROM MOUTH, ALWAYS ABLE TO BREATHE, EYES GLAZED, STARING, UNRESPONSIVE TO HER NAME, LASTED 1 MINUTE. CHILD CONTINUED TO TAKE THE REMEDY UNTIL PRESENT. THERE WAS ONLY ONE INCIDENT OF THE SEIZURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

10285322-01-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

~~SECTION II:~~ ~~INVESTIGATION:~~

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/20/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

DSS

JUL 0 3 2014

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1544

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/20/14

BY: TUTTI GOULD

SECTION V:

JUL 02 2014

REVIEWED BY MANAGEMENT BY:

DATE: 06-25-14

BY:

QA / QC DIRECTOR

DATE: 06-25-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

Individual Case Safety Report

10285322-01-00-04

VDARD ATHIC SA SINCE 1903

verse Event

J20-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been sixty-four Adverse Events (AE) which also included ten Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tables. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

6/23/14
Date

DSS

JUL 0 3 2014

JUL 02 2014

CC-0416-2014
AE-0233-2014
SAE# 161

CaseID: 10285322

Individual Case Safety Report

10285322-01-00-05

Hyland's

EVENT DATA FORM

AE #: 1544 COMPLAINT #: 2554

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

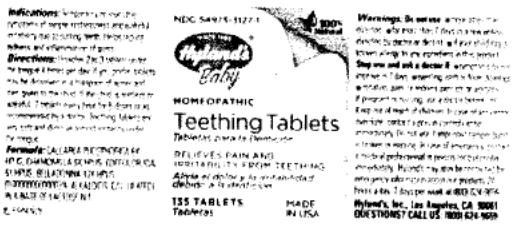
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

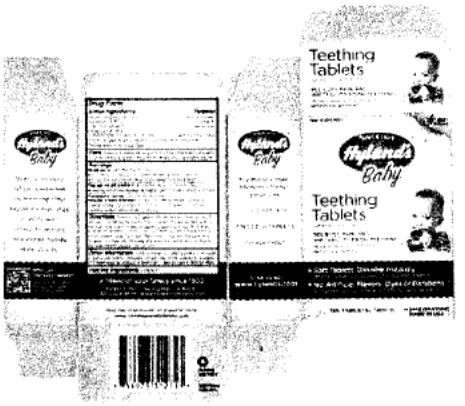
E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: CORRECTIVE ACTION:

DSS

CORRECTIVE ACTION(S) COMPLETED BY: DATE: JUL 03 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWatt DATE: 06-24-14

BY: Eric Baum DATE: 06-23-14
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FDA SAE JUL 02 2014

CaseID: 10285323

Individual Case Safety Report

10285323-01-00-01

OTC

er-facilities, s and manufacturers DRY reporting

Form Approved: OMB No. 09 10-029 1. Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973 page 2

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: 3 1\2 Months or Date of Birth:	3. Sex	4. Weight
		☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
05/00/2014 -- 06/17/2014	06/20/2014

5. Describe Event or Problem

REPORTER STATES HER SON WOULD HAVE A DRY MOUTH AFTER GIVING THE TEETHING TABLTS TO HIM AND THAT HIS BODY INCLUDING LIMBS WOULD SHAKE ALL OVER AND KEEP SHAKING. REPORTS SAYS THIS WOULD OCCUR RIGHT AFTER GIVING THE TABLETS TO HER SON, AND THAT SYMPTOMS (DRY MOUTH AND SHAKING) WOULD LAST 10 - 15 MINUTES BEFORE STOPPING.

6. Relevant Tests/Laboratory Data, Including Dates

NONE

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD HAS A HOLE IN HIS HEART. NO MEDICATIONS OR TREATMENTS, HAVE TO TAKE HIM TO A HEART DOCTOR IN THE FUTURE.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1 TAB SL PRN;UP TO 4X/DY	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 B27313	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

JUL 03 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

Phone # (b) (6)

(b) (6)

JUL 02 2014

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☐ Unk.

FDA USE ONLY

F. FOR USE BY USER FACILITY, IMPORTER OR DISTRIBUTOR

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # _____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code _____ - _____ - _____; Device Code _____ - _____ - _____
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/10/2014
5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): DRY MOUTH AND SHAKING
9. Manufacturer Report Number: 54973 AE # 1543

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: _____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method _____ - _____ - _____ - _____; Results _____ - _____ - _____ - _____; Conclusions _____ - _____ - _____ - _____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: _____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

JUL 03 2014

JUL 02 2014

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

ID: 10285323

SECTION I: **COMPLAINT**

COMPLAINT #: 2553

TAKEN BY: (b) (6)

DATE OF COMPLAINT: 06/19/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABLETS

LOT NO.: B27313

REPORTER: (b) (6)

RECEIVED
JUL 02 2014
CDR

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CALLED BECAUSE SHE SAW SOMETHING ON FACEBOOK ABOUT THE PRODUCT BEING RECALLED AND IT CAUSING SEIZURES IN CHILDREN. WANTED INFORMATION. AFTER PROVIDING SAFETY INFORMATION, SAID THAT SHE NOTICED HER SON WOULD HAVE A DRY MOUTH AFTER GIVING THE TEETHING TABLETS TO HIM AND THAT HIS BODY INCLUDING LIMBS WOULD SHAKE ALL OVER AND KEEP SHAKING. REPORTER SAYS THIS WOULD OCCUR RIGHT AFTER GIVING THE TABLETS TO HER SON, AND THAT SYMPTOMS (DRY MOUTH AND SHAKING) WOULD LAST 10 – 15 MINUTES BEFORE STOPPING. REPORTER STATES THIS OCCURRED EVERY TIME SHE GAVE THE CHILD THE PRODUCT, UP TO FOUR TIMES PER DAY WHEN DOSING THE PRODUCT, UNTIL SHE DISCONTINUED THE PRODUCT. UNSURE OF THE EXACT NUMBER OF TIMES THE CHILD EXPERIENCED THESE SYMPTOMS. THE CHILD HAS NOT HAD A DRY MOUTH OR ANY SHAKING SINCE STOPPING THE PRODUCT A FEW DAYS AGO. ADVISED REPORTER TO CONTACT THEIR PHYSICIAN TO DISCUSS SYMPTOMS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

Individual Case Safety Report

10285323-01-00-03

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/19/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: **CORRECTIVE ACTION:**

DSS
JUL 08 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1543

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/20/14 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 06-24- JUL 02 2014

BY: Eric Baum QA / QC DIRECTOR DATE: 06-23-14

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

Individual Case Safety Report

10285323-01-00-04

YDARD
ATHIC
A SINCE 1903

/erse Event
21-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B27313, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B27313 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B27313. The Baby Teething bulk lot # 121648 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # B27313, however a each of lots manufactured using the same bulk lot (121648) did reveal seven complaints (CC-0886-2013, CC-0059-2014, CC-0066-2014, CC-0122-2014, CC-0123-2014, CC-0200-2014 & CC-0239-2014). The complaints were reviewed and although there was one that was similar and also reported as an SAE (CC-0066-2014) there does not appear to be a trend related to this bulk lot. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B27313.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/23/2014
Date

DSS
JUL 0 3 2014

JUL 02 2014

CC-0418-2014
AE-0235-2014

CaseID: 10285323

STANDARD
Individual Case Safety Report

10285323-01-00-05

Hyland's

ENT DATA FORM

AE #: 1543 COMPLAINT #: 2553

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

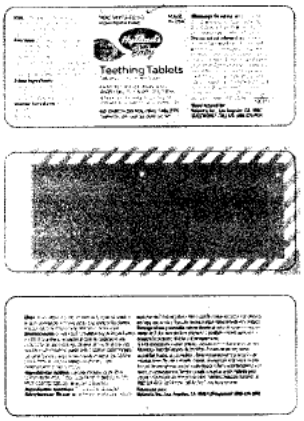
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY: DATE: JUL 03 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-24 JUL 02 2014

BY: Eric Bauer DATE: 06-23-14
QA / QC DIRECTOR
06-23-14
EJB 06-23-14

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

10302306-01-00-01

CaseID: 10302306

Form Approved: OMB No. 0910-0291, Expires: 3/31/2016
See OMB statement on reverse.

e by user facilities, ibutors and manufacturers DATCP reporting

OTC

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	10 Months	☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/24/2014	06/26/2014

5. Describe Event or Problem

CHILD WITH SEIZURE LIKE ACTIVITY THAT RESOLVED WHEN BABY TEETHING TABLETS WERE DISCONTINUED.

Received
JUL 09 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

UNSPECIFIED TESTS CONDUCTED BY PHYSICIAN; RESULTS WERE NORMAL

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 UNKNOWN DOSE X 6 MONTHS	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF OF TEETHING PAIN	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 B27213	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

USA

DSS
JUL 10 2014

Phone #	Email Address (b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

JUL 09 2014

Individual Case Safety Report

CaseID: 10302306

10302306-01-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | 5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy) | 7. Type of Report ☐ Initial ☐ Follow-up # ____ | 8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device | 10. Event Problem Codes (Refer to coding manual) Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___

11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ (Specify)

13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply)
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 06/24/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURE LIKE ACTIVITY

9. Manufacturer Report Number: 54973 AE # 1549

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes (Refer to coding manual)
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

JUL 10 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

JUL 09 2014

Individual Case Safety Report

COMPLAINT RECORD

D: 10302306

10302306-01-00-03

COMPLAINT #: 2559

DATE OF COMPLAINT: 06/24/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T40

SIZE: 40 TABLETS

LOT NO.: B27213

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #:

E-MAIL: (b) (6)

NATURE OF COMPLAINT: CUSTOMER SENT E-MAIL THAT HER CHILD HAD SEIZURE LIKE ACTIVITY WHILE USING HYLAND'S BABY TEETHING TABLETS. TAKEN TO A NEUROLOGIST AND TESTS WERE NORMAL. SEIZURE ACTIVITY STOPPED AFTER BABY TEETHING TABLETS WERE DISCONTINUED. CUSTOMER SENT E-MAIL THAT LOT # IS B27213 AND CHILD BEGAN USING THE TABLETS WHEN HE WAS ABOUT 4 MONTHS. IS NOW 10 MONTHS. HAS NOT CONTACTED HYLAND'S BY PHONE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 06/24/2014

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1549

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/24/2014 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 07-01-14

BY: Eric Bain QA / QC DIRECTOR DATE: 07-01-14

DSS

JUL 10 2014

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

JUL 09 2014

10302306-01-00-04

ANDARD
OPATHIC
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s Adverse Event
SAE-0026-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B27213, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B27213 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B27213. The Baby Teething bulk lot # 121648 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured three other customer complaints (CC-0123-2014, CC-0239-2014 & CC-0409-2014) have been received for Hyland's Baby Teething Tablets lot # B27213. The complaints were reviewed and there does not appear to be a trend related to this lot. We will continue to monitor our reported incidents for potential trends. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B27213.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/26/2014
Date

DSS
JUL 10 2014

CC-0435-2014
AE-0251-2014

JUL 09 2014

10302306-01-00-05

SE EVENT DATA FORM

AE #: 1549 **COMPLAINT #:** 2559

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

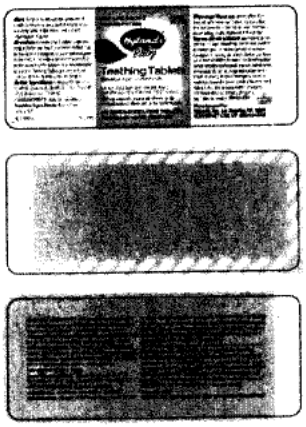
COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
JUL 10 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 07-01-14

BY: Eric Brun DATE: 07-01-14
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUL 09 2014

Individual Case Safety Report

10302334-01-00-01

CaseID: 10302334

OTC

by user-facilities, butors and manufacturers DATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

FORM FDA 3500A (2/13) Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	7 Months	☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
02/00/2014 - PRESENT	06/24/2014

5. Describe Event or Problem

CHLD HAS BEEN EXPERIENCING SEIZURES FOR THE PAST 4 MONTHS. DESCRIBED AS CHILD STARTS SHAKING AND EYES ROLL BACK IN HIS HEAD.

Received
JUL 09 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

06/24/14: MOTHER SAID SHE STOPPED BABY TEETHING TABLETS ON 06/18/14 AND CHILD HAD A SEIZURE ON 06/24/14 THAT LASTED 10 SECONDS.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 1 TAB SL QD X 4 MONTHS	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 B50413	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Unique Identifier (UDI) #	☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

DSS
JUL 10 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

JUL 09 2014

FDA USE ONLY

1. Check One: ☐ User Facility ☐ Importer

2. Of/Importer Report Number(s)

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report: ☐ Initial ☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code _____ - _____ - _____

Device Code _____ - _____ - _____

11. Report Sent to FDA?

☐ Yes _____ *(mm/dd/yyyy)*

☐ No

12. Location Where Event Occurred

☐ Hospital ☐ Outpatient Diagnostic Facility

☐ Home

☐ Nursing Home ☐ Ambulatory Surgical Facility

☐ Outpatient Treatment Facility

☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?

☐ Yes _____ *(mm/dd/yyyy)*

☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address:

HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*

☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/19/2014

5. (A)NDA # _____

IND # _____

BLA # _____

PMA/510(k) # _____

Combination Product ☐ Yes

Pre-1938 ☐ Yes

OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*

☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURES

9. Manufacturer Report Number: 54973 AE # 1546

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event

☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?

☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?

☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?

☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*

Patient Code _____ - _____ - _____

Device Code _____ - _____ - _____

Method _____ - _____ - _____ - _____

Results _____ - _____ - _____ - _____

Conclusions _____ - _____ - _____ - _____

7. If Remedial Action Initiated, Check Type

☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: _____

8. Usage of Device

☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

JUL 10 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

JUL 09 2014

Individual Case Safety Report

:OMPLAINT RECORD

10302334

10302334-01-00-03

COMPLAINT #: 2556

DATE OF COMPLAINT: 06/19/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: B50413

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: MALE CHILD IS 7 MONTHS OLD. WAS GIVING THE TEETHING TABLETS 1 TABLET EVERY DAY X 4 MONTHS. STARTED HAVING SEIZURES SINCE HE WAS 2 OR 3 MONTHS OLD. STOPPED USING THE TEETHING TABLETS YESTERDAY WHEN SHE SAW A FACEBOOK POST. CHILD STARTS SHAKING AND EYES ROLL BACK IN HIS HEAD. IS GOING TO CONTACT AN ATTORNEY. TOLD HER THAT SHE WAS USING TABLETS FOR LONGER THAN RECOMMENDED. PROVIDED INFORMATION ABOUT BABY TEETHING TABLETS AND INGREDIENTS IN THE TEETHING TABLETS. TOLD HER THAT THERE IS NO CURRENT RECALL ON BABY TEETHING TABLETS. ATTEMPTED TO CALL CUSTOMER FOR FOLLOW-UP ON 06/22 AND 06/23 BUT NO ANSWER SO LEFT A MESSAGE.
06/24/14 FOLLOW-UP: CONTACTED THE CUSTOMER FOR FOLLOW-UP INFORMATION AND SHE TOLD ME SHE HAD STOPPED BABY TEETHING TABLETS ON 06/18/14 AND THAT CHILD HAD A SEIZURE ON 06/24/14 THAT LASTED 10 SECONDS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

06/22/14: ATTEMPTED TO CALL CUSTOMER FOR FOLLOW-UP; NO ANSWER; LEFT A MESSAGE.
06/23/14: ATTEMPTED TO CALL CUSTOMER FOR FOLLOW-UP; NO ANSWER; LEFT A MESSAGE.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 06/19/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1546

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/19/14

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-27-14

BY: Erin Baum
QA / QC DIRECTOR

DATE: 06-27-14

DSS
JUL 10 2014

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

JUL 09 2014

10302334-01-00-04

STANDARD HOMEOPATHIC
THE USA SINCE 1903

...s Adverse Event
SAE-0023-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B50413, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B50413 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis including microbial results were reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B50413. The Baby Teething bulk lot # 121648 was tested for total Atropine and Scopolamine and the results were with in specification of (b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other customer complaints have been received for Hyland's Baby Teething Tablets lot # B50413.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B50413.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/26/2014
Date

DSS
JUL 10 2014

CC-0426-2014
AE-0242-2014

JUL 09 2014

10302334-01-00-05

RSE EVENT DATA FORM

AE #: 1546 **COMPLAINT #:** 2556

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

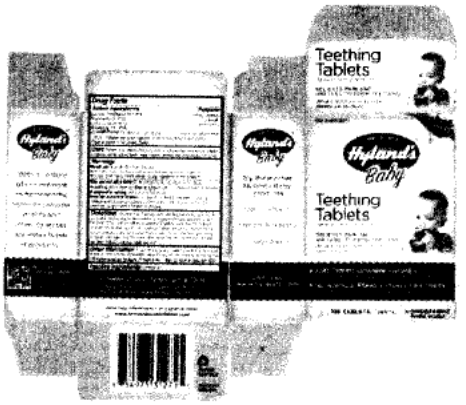
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-27-14

BY: QA / QC DIRECTOR DATE: 06-27-14

DSS JUL 10 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUL 09 2014

FORM SAE01

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

10302341-01-00-01

OTC

by user-facilities,
butors and manufacturers
DATORY reporting

MFR Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence

2. Age at Time of Event: 6 Months or Date of Birth:

3. Sex: ☐ Female ☑ Male

4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: ____ (mm/dd/yyyy)
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 05/24/2014 -- PRESENT

4. Date of This Report (mm/dd/yyyy): 06/24/2014

5. Describe Event or Problem

CHILD STARTED HAVING TREMORS FROM HEAD TO TOE (MINI SEIZURES) MEMORIAL DAY WEEKEND AND THE SEIZURES ARE COMING MORE FREQUENTLY, ALMOST ON DAILY BASIS.

Received
JUL 09 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

EEG RESULTS INCONCLUSIVE

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

GRANDMOTHER'S SON (CHILD'S UNCLE) HAS A HISTORY OF SEIZURE DISORDER

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 3 TABS QD X 2 MONTHS
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 109341
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

5. Operator of Device
☐ Health Professional
☐ Lay User/Patient
☐ Other:

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Unique Identifier (UDI) #

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

DSS
JUL 10 2014

Phone # (b) (6)

Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☑ Unk.

JUL 09 2014

Individual Case Safety Report

CaseID: 10302341

10302341-01-00-02

FDA USE ONLY

1. Check One: ☐ User Facility ☐ Importer

2. Dr/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report: ☐ Initial ☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code _____ – _____ – _____
Device Code _____ – _____ – _____

11. Report Sent to FDA?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home
☐ Nursing Home ☐ Ambulatory Surgical Facility
☐ Outpatient Treatment Facility
☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address:
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other: _____

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/20/2014

5.
(A)NDA # _____
IND # _____
BLA # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973 AE # 1547

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: _____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code _____ – _____ – _____
Device Code _____ – _____ – _____
Method _____ – _____ – _____ – _____
Results _____ – _____ – _____ – _____
Conclusions _____ – _____ – _____ – _____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: _____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUL 10 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

JUL 09 2014

10302341-01-00-03

COMPLAINT RECORD

0302341

COMPLAINT #: 2557

DATE OF COMPLAINT: 06/20/2014

PRODUCT: HYLAND'S TEETHING TABLETS

ITEM CODE: TEET----T125

SIZE: 125 TABLETS

LOT NO.: 109341

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CALLER'S GRANDSON STARTED TEETHING IN MAY. THE WEEKEND OF MEMORIAL DAY CHILD STARTED HAVING TREMORS FROM HEAD TO TOE (MINI SEIZURES). SEIZURES COMING MORE FREQUENTLY ALMOST ON DAILY BASIS. EEG WAS SET UP. STILL HAVING SEIZURES AND GOT HIS FIRST TOOTH. GRANDMOTHER'S SON HAS SEIZURE DISORDER. DAUGHTER WAS GIVING 3 TABS EVERY DAY SINCE APRIL. LAST DOSE WAS YESTERDAY AFTER SHE SAW THE FACEBOOK POST. DOES NOT WANT A REFUND OR REPLACEMENT EVEN AFTER I OFFERED IT TO HER. SHE CONFIRMED THAT SHE PURCHASED THIS RECALLED BOTTLE AT WALMART IN FEBRUARY 2014. SHE WANTED TO READ LITERATURE ON THE 2010 RECALL OF HYLAND'S TEETHING TABLETS AND I DIRECTED HER TO THE FDA WEBSITE AND WWW.HYLANDS.COM. TOLD HER NOT TO USE THE TABLETS. TOLD HER THE REASONS FOR THE 2010 RECALL. TOLD HER THAT SHE HAS A RECALLED BOTTLE AND NOT TO USE. SHE SAID THAT SHE WILL NOT BE USING THE TABLETS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/20/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1547

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/20/14

BY: EDYTA FRACKIEWICZ

DSS

JUL 10 2014

SECTION V:

REVIEWED BY MANAGEMENT BY: RWaff

DATE: 07-01-14

BY: Gina Bacci
QA / QC DIRECTOR

DATE: 06-30-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

JUL 09 2014

10302341-01-00-04

ANDARD
OPATHIC
HE USA SINCE 1903

s Adverse Event
SAE-0024-2014

Product in Inventory:

No units of Hyland's Teething Tablets (TEET), lot # 109341, are currently in the Standard Homeopathic Co. (SHC) warehouse. This lot was a part of the Teething Tablets recall performed by SHC and was withdrawn from the market in 2010.

Review of Records:

The Hyland's Teething Tablets (TEET), lot # 109341 associated manufacturing and packaging records were reviewed and did not reveal any issues.

Retention Samples:

No retention sample for this lot could be located and therefore an inspection was not possible

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other customer complaints have been received for of Hyland's Teething Tablets (TEET), lot # 109341.

Conclusion:

Hyland's Teething Tablets (TEET), lot # 109341 was subject to an SHC recall and withdrawn from the market in 2010.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/27/14
Date

DSS
JUL 10 2014

CC-0430-2014
AE-0245-2014
SAE 164

JUL 09 2014

10302341-01-00-05

RSE EVENT DATA FORM

AE #: 1547 COMPLAINT #: 2557

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 07-01-14

BY: Eric Brun DATE: 06-30-14
QA / QC DIRECTOR

DSS JUL 10 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUL 09 2014

Individual Case Safety Report

10302641-02-00-01

CaseID: 10302641

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

ser-facilities
rs and manufacturers
ORY reporting

OTC

Mfr Report # 54973 AE # 1545

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	1 Years	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/12/2014 -- 06/19/2014	06/24/2014

5. Describe Event or Problem

GAVE CHILD A FEW MOLDY TABLETS (1 TAB AM AND 1 TAB PM) A WEEK AGO 06/12/14 AND AFTER THE EVENING DOSE ABOUT 15 MINUTES LATER HE WOKE UP AND HE WAS SHAKING, EYES ROLLED IN BACK OF HEAD, WOULD NOT STOP CRYING, WOULD NOT GO TO SLEEP. HAS BEEN ACTING WEIRD SINCE THEN - FUSSY, AND EVERY OTHER NIGHT WAKING UP IN THE MIDDLE OF THE NIGHT SHAKING, EYES ROLLING BACK OF HEAD, NOT SLEEPING, CRYING.

Received
OCT 23 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 1 TAB QD OR BID X 2 MOS.	#1
#2	#2

4. Diagnosis for Use *(Indication)*
#1 TEMP RELIEF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 A79913	#1
#2	#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Unique Identifier (UDI) #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
OCT 24 2014

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

OCT 23 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

CaseID: 10302641

10302641-02-00-02

f 10

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/19/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #:
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☑ Follow-up # 1
8. Adverse Event Term(s): SEIZURE LIKE ACTIVITY, SLEEPLESSNESS, CRYING, FUSSY
9. Manufacturer Report Number: 54973 AE # 1545

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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OCT 24 2014

OCT 23 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hylands

10302641

SECTION I: **COMPLAINT**

COMPLAINT #: 2555

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/19/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABLETS

LOT NO.: A79913

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: TABLETS BECAME MOLDY. WAS GIVING 1 TABLET QD X 2 MONTHS. GAVE CHILD A FEW MOLDY TABLETS (1 TAB AM AND 1 TAB PM) A WEEK AGO 06/12/14 AND AFTER THE EVENING DOSE ABOUT 15 MINUTES LATER HE WOKE UP AND WAS SHAKING, EYES ROLLED IN BACK OF HEAD, WOULD NOT STOP CRYING, WOULD NOT GO TO SLEEP. HAS BEEN ACTING WEIRD SINCE THEN-FUSSY, AND EVERY OTHER NIGHT WAKING UP IN THE MIDDLE OF THE NIGHT SHAKING, EYES ROLLING BACK OF HEAD, NOT SLEEPING, CRYING. HER FRIENDS HAVE ALSO COMPLAINED ABOUT THE BABY TEETHING TABLETS BEING MOLDY. DID NOT WANT A REPLACEMENT. WANTS A REFUND FOR $ 4. WE WILL SEND A REFUND. DO NOT USE MOLDY TABLETS. CONTACT YOUR DOCTOR REGARDING THE SYMPTOMS. TOLD HER SHE HAS BEEN USING THE PRODUCT FOR LONGER THAN DIRECTED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

10302641-02-00-03

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 06/19/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

06/26/14: PREPARED REFUND REQUEST TOTALING $ 4.00. 07/16/14: MAILED REFUND CHECK # 511649 TOTALING $ 4.00.

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OCT 24 2014

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6)

DATE: 07/16/14

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1545

OCT 23 2014

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/19/14

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt

DATE: 10-02-14

BY: Eric Bonin
QA / QC DIRECTOR

DATE: 09-30-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

CaseID: 10302641

Mailed on 07/16/14
CC-0425-2014
SAE-0033-2014

STANDARD HOMEOPATHIC

June 26, 2014

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $4.00. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $4.00

Individual Case Safety Report
10302641-02-00-04

DSS
OCT 24 2014

OCT 23 2014

Standard Homeopathic Company • Setting the Standard in Homeopathy, Since 1903
210 West 131st Street • P.O. Box 61067 • Los Angeles, CA 90061 • (310) 768-0700 • fax (310) 516-8579

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

10302641

mailed 07/03/14 article no. 70081140000501696875

SECTION I: **COMPLAINT**

COMPLAINT #: 2555

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/19/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABLETS

LOT NO.: A79913

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: TABLETS BECAME MOLDY. WAS GIVING 1 TABLET QD X 2 MONTHS. GAVE CHILD A FEW MOLDY TABLETS (1 TAB AM AND 1 TAB PM) A WEEK AGO 06/12/14 AND AFTER THE EVENING DOSE ABOUT 15 MINUTES LATER HE WOKE UP AND WAS SHAKING, EYES ROLLED IN BACK OF HEAD, WOULD NOT STOP CRYING, WOULD NOT GO TO SLEEP. HAS BEEN ACTING WEIRD SINCE THEN-FUSSY, AND EVERY OTHER NIGHT WAKING UP IN THE MIDDLE OF THE NIGHT SHAKING, EYES ROLLING BACK OF HEAD, NOT SLEEPING, CRYING. HER FRIENDS HAVE ALSO COMPLAINED ABOUT THE BABY TEETHING TABLETS BEING MOLDY. DID NOT WANT A REPLACEMENT. WANTS A REFUND FOR $ 4. WE WILL SEND A REFUND. DO NOT USE MOLDY TABLETS. CONTACT YOUR DOCTOR REGARDING THE SYMPTOMS. TOLD HER SHE HAS BEEN USING THE PRODUCT FOR LONGER THAN DIRECTED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

10302641-02-00-06

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/19/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: OCT 24 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1545

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/19/14

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-27-14 OCT 23 2014

BY: QA / QC DIRECTOR

DATE: 06-27-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0022-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A79913, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A79913 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification including the mold results for Hyland's Baby Teething Tablets lot # A79913. The Baby Teething bulk lot # 120264 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other SAE (SAE-0041-2013) has been received for Hyland's Baby Teething Tablets lot # A79913. The complaints were reviewed and although they do indicate similar reactions there does not appear to be a trend related to this lot. We will continue to monitor our reported incidents for potential trends. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A79913.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/27/2014
Date

DSS
OCT 24 2014

Individual Case Safety Report
10302641-02-00-07

OCT 28 2014

CC-0418-2014
AE-0235-2014

CaseID: 10302641

10302641-02-00-08

ADVERSE EVENT DATA FORM

Initiated By: EDYTA FRACKIEWICZ Date: 6/19/2014

AE #: 1545 Complaint #: 2555

A. PATIENT INFORMATION

1. Patient Identifier (In confidence)

(b) (6)

Phone # or E-mail Address

2. Age at Time of Event: 1 YEAR OLD

OR

Date of Birth: / /

3. Sex ☐ Female ■ Male

4. Weight: _____ lbs.

OR

_____ kgs.

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ■ Adverse Event and/or ☐ Product Problem (e.g.. defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death _____
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent
- ☐ Congenital Anomaly/Birth Defect
- ■ Other Serious (Important Medical Events)
- ☐ Required intervention to Prevent Permanent Impairment/ Damage (Devices)
- ☐ None

3. Date of Event (mm/dd/yyyy): 06/12/2014 -- 06/19/2014

Time of Event:

4. Date Submitted to FDA (mm/dd/yyyy): 07/03/2014

5. Pre-existing Conditions / Diagnosis: NONE

6. Describe Event or Problem:

GAVE CHILD A FEW MOLDY TABLETS (1 TAB AM AND 1 TAB PM) A WEEK AGO 06/12/14 AND AFTER THE EVENING DOSE ABOUT 15 MINUTES LATER HE WOKE UP AND HE WAS SHAKING, EYES ROLLED IN BACK OF HEAD, WOULD NOT STOP CRYING, WOULD NOT GO TO SLEEP. HAS BEEN ACTING WEIRD SINCE THEN - FUSSY, AND EVERY OTHER NIGHT WAKING UP IN THE MIDDLE OF THE NIGHT SHAKING, EYES ROLLING BACK OF HEAD, NOT SLEEPING, CRYING.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used

#1 1 TABLET EVERY DAY OR TWICE A DAY X 2 MONTHS

#2

D. INITIAL REPORTER

1. Name and Address (b) (6) Phone #: (b) (6)

2. Health Professional? ☐ Yes ■ No ■ Consumer

3. Occupation: MOTHER

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ■ Unknown

G. ALL MANUFACTURERS

1. Contact Office - Name/Address

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number 310-768-0700

3. Report Source (Check all that apply)

- ☐ Foreign
- ☐ Study
- ☐ Literature
- ■ Consumer
- ☐ Health Profl.
- ☐ User Facility
- ☐ Company Rep.
- ☐ Distributor
- ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 06/19/2014

5. DSS OCT 24 2014

(A)NDA # _____

IND # _____

STN # _____

PMA/510(k) # _____

Combination Product ☐ Yes

Pre-1938 ☐ Yes

OTC Product ■ Yes

6. If IND, Give Protocol

7. Type of Report (Check all that apply)

- ☐ 5-day
- ☐ 7-day
- ☐ 10-day
- ■ 15-day
- ☐ 30-day
- ☐ Periodic
- ■ Initial
- ☐ Follow-up # _____

OCT 28 2014

8. Adverse Event Term(s): SEIZURE LIKE ACTIVITY, SLEEPLESSNESS, CRYING, FUSSY

9. Manufacturer Report Number (AE #): 54973 AE # 1545

CaseID: 10302641

10302641-02-00-09

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

: by user-facilities,
ibutors and manufacturers
DATORY reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

MEDWATCH

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: 1 Years or Date of Birth:	3. Sex ☐ Female ☑ Male	4. Weight ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/12/2014 -- 06/19/2014	06/24/2014

5. Describe Event or Problem

GAVE CHILD A FEW MOLDY TABLETS (1 TAB AM AND 1 TAB PM) A WEEK AGO 06/12/14 AND AFTER THE EVENING DOSE ABOUT 15 MINUTES LATER HE WOKE UP AND HE WAS SHAKING, EYES ROLLED IN BACK OF HEAD, WOULD NOT STOP CRYING, WOULD NOT GO TO SLEEP. HAS BEEN ACTING WEIRD SINCE THEN - FUSSY, AND EVERY OTHER NIGHT WAKING UP IN THE MIDDLE OF THE NIGHT SHAKING, EYES ROLLING BACK OF HEAD, NOT SLEEPING, CRYING.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1 TAB QD OR BID X 2 MOS.	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A79913	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

DSS
OCT 24 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

OCT 23 2014

Phone # (b) (6)	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

CaseID: 10302641

10302641-02-00-10

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/19/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #:
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURE LIKE ACTIVITY, SLEEPLESSNESS, CRYING, FUSSY
9. Manufacturer Report Number: 54973 AE # 1545

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type?: ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
OCT 24 2014

OCT 23 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report

10307987-01-00-01

CaseID: 10307987

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

y user-facilities,
itors and manufacturers
ATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13) Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	2 Years	☐ Female	____ lbs
In confidence	or Date of Birth:	☑ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
00/00/2014	06/26/2014

5. Describe Event or Problem

CHILD WITH SPEECH DELAY REQUIRES THERAPY.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 UNKNOWN DOSE FOR 1 YEAR	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

RECEIVED JUL 10 2014 CDR

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Unique Identifier (UDI) #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: JUL 11 2014 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

JUL 10 2014

Phone #	Email Address (b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

PLEASE TYPE OR USE BLACK INK

FDA USE ONLY

1. Check One: ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report: ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

11. Report Sent to FDA?

☐ Yes ____ *(mm/dd/yyyy)*

☐ No

12. Location Where Event Occurred

☐ Hospital ☐ Outpatient Diagnostic Facility

☐ Home ☐ Ambulatory Surgical Facility

☐ Nursing Home

☐ Outpatient Treatment Facility

☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?

☐ Yes ____ *(mm/dd/yyyy)*

☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address:

HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*

☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/22/2014

5. (A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*

☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SPEECH DELAY

9. Manufacturer Report Number: 54973 AE # 1548

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event

☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?

☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?

☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?

☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type

☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device

☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

JUL 11 2014

JUL 10 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report

10307987-01-00-03

...MPLAINT RECORD

10307987

COMPLAINT #: 2558

DATE OF COMPLAINT: 06/22/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: NOT PROVIDED

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #:

E-MAIL: (b) (6)

NATURE OF COMPLAINT: MOTHER SENT E-MAIL THAT CHILD USING TEETHING TABLETS FROM BIRTH TO ONE YEAR OF AGE. CHILD 2 YEARS OLD AND HAS BAD SPEECH DELAY AND GOING TO THERAPY. MOTHER DID NOT RESPOND TO E-MAIL SENT BY PHARMACIST AND DID NOT CALL CELL PHONE OF PHARMACIST.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 06/22/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS

JUL 11 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 15448

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/22/14

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: R Watt

DATE: 06-30-14

BY: Gina Brun
QA / QC DIRECTOR

DATE: 06-30-14

JUL 10 2014

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

Individual Case Safety Report

ID: 10307987

10307987-01-00-04

VENT DATA FORM

AE #: 1548 **COMPLAINT #:** 2558

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

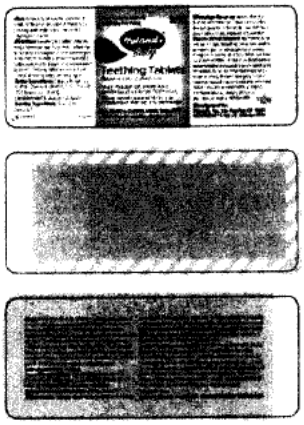
COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY: DATE: JUL 11 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-30-14

BY: QA / QC DIRECTOR DATE: 06-30-14 JUL 10 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

NDARD
PATHIC
USA SINCE 1903

Serious Adverse Event
SAE-0025-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-nine Adverse Events (AE) which also included twenty-one Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tables. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

6/27/14
Date

DSS
JUL 11 2014

JUL 10 2014

Individual Case Safety Report

10313881-01-00-01

by user-facilities, ibutors and manufacturers DATORY reporting

OTC

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Case ID: 10313881

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	13 Months	☐ Female	____ lbs
In confidence	or ____ Date of Birth:	☑ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/25/2014	06/30/2014

5. Describe Event or Problem

CUSTOMER POSTED ON (b) (6) THAT ON WED JUNE 25TH 20 MIN AFTER GIVING HER 13 MONTH OLD 2 TEETHING TABLETS WENT INTO SEIZURE. SINCE THEN HE'S HAD HIGH FEVERS, VOMITING, RAPID HEARTBEAT, MUSCLE WEAKNESS, RASH, DAZED/CONFUSION, IRRITABILITY, TIREDNESS, LETHARGY.

JUL 16 2014

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNKNOWN

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 2 TABS ON 06/25/14	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

JUL 17 2014

USA

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 10313881

10313881-01-00-02

of 5

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One
☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
EDYTA FRACKIEWICZ
Address
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address
STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
06/30/2014

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
Seizure, fevers, vomiting, tachycardia, muscle weakness, rash, confusion, irritability, lethargy

9. Manufacturer Report Number
54973 AE # 1552

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUL 17 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.".

JUL 16 2014

Individual Case Safety Report

10313881-01-00-03

COMPLAINT RECORD

ID: 10313881

COMPLAINT #: 2562

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/30/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY:

ZIP CODE:

PHONE #: NOT PROVIDED

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER POSTED ON (b) (6) ON WED JUNE 25TH 20 MIN AFTER GIVING HER 13 MONTH OLD 2 TEETHING TABLET WENT INTO SEIZURE. SINCE THEN HE'S HAD HIGH FEVERS, VOMITING, RAPID HEARTBEAT, MUSCLE WEAKNESS, RASH, DAZED/CONFUSION, IRRITABILITY, TIREDNESS, LETHARGY. IT WAS YOU PRODUCT THAT HAS CAUSED THIS. CUSTOMER DID NOT RESPOND TO HYLAND'S REQUEST TO CONTACT THE COMPANY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1552

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/30/14 BY: EDYTA FRACKIEWICZ

DSS

JUL 17 2014

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 07-08-14

BY: QA / QC DIRECTOR DATE: 07-08-14

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

JUL 16 2014

Serious Adverse Event
SAE-0029-2014

Product in Inventory:

The reporter was only able to provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved, a review the customer complaints and Deviation systems is not possible. Although the lot number of the unit involved cannot be determined, Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum was "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Standard Homeopathic Company will continue to monitor other adverse events related to our Teething products to ensure that significant trends can be observed in a timely manner.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Eric Bauer
Prepared by

07-07-14
Date

DSS
JUL 17 2014

AE # 1552
Complaint # 2562
CC-0460-2014
AE-0260-2014
SAE-0029-2014

JUL 16 2014

Individual Case Safety Report

CaseID: 10313881

10313881-01-00-05

Hyland's

EVENT DATA FORM

AE #: 1552

COMPLAINT #: 2562

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

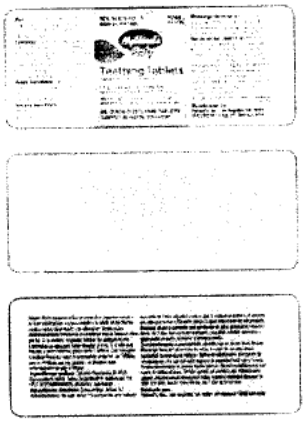
COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS

JUL 17 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 07-08-14

BY: DATE: 07-08-14

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUL 16 2014

Individual Case Safety Report

10314685-01-00-01

CaseID: 10314685

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

For use by user-facilities, s, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event: 18 Months or Date of Birth:
3. Sex: [x] Female [ ] Male
4. Weight: 20-22 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- [ ] Death: (mm/dd/yyyy)
- [ ] Disability or Permanent Damage
- [ ] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [x] Hospitalization - initial or prolonged
- [x] Other Serious (Important Medical Events)
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 10/00/2013

4. Date of This Report (mm/dd/yyyy): 06/25/2014

5. Describe Event or Problem

CHILD HAD SEIZURE IN (b) (6) SEIZURES OCCURRED EARLY IN THE MORNING AND EACH EPISODE GOT PROGRESSIVELY WORSE. CHILD TAKEN TO HOSPITAL AND CONTINUED TO HAVE SEIZURES IN THE HOSPITAL. HOSPITALIZED FOR 4 DAYS. CHILD WAS "PUKING" AND WENT TO HOSPITAL THE DAY BEFORE. BABY TOOK NAUSEA AND VOMITING MEDICINES. NEXT DAY SHE HAD SEIZURE. NO SEIZURES SINCE ORIGINAL EPISODE.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

EEG -- NORMAL
PRESCRIBED DIAZEPAM 5MG SUPPOSITORIES

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NO KNOWN FOOD ALLERGIES
NO KNOWN MEDICATION ALLERGIES
NO KNOWN ENVIRONMENTAL ALLERGIES

FOLLOW-UP 1 MONTH LATER WAS "NOTHING ELSE WRONG".
FOLLOW-UP IN 1 YEAR AND GO FROM THERE.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 INTERMITTENTLY Q 3-4 HRS
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF OF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [x] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [x] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID
54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
UNKNOWN NAUSEA AND VOMITING MEDICATION (ONE DOSE)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
2b. Procode
3. Manufacturer Name, City and State
4. Model #
Lot #
Catalog #
Expiration Date (mm/dd/yyyy)
Serial #
Unique Identifier (UDI) #
5. Operator of Device
[ ] Health Professional
[ ] Lay User/Patient
[ ] Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

JUL 18 2014

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

JUL 17 2014

Phone # (b) (6)
Email Address
2. Health Professional? [ ] Yes [x] No
3. Occupation: NA
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [x] No [ ] Unk.

10314685-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/25/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #:
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURES
9. Manufacturer Report Number: 54973 AE # 1551

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUL 18 2014

JUL 17 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

10314685

IER COMPLAINT RECORD

10314685-01-00-03

COMPLAINT #: 2561

TAKEN BY: (b) (6)

DATE OF COMPLAINT: 06/25/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: DOESN'T HAVE BOTTLE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: MOTHER / REPORTER CALLED THE PIS PHONE LINE TO DISCUSS THE TEETHING TABLET RUMOR. ONE OF HER CHILDREN HAD A SEIZURE EPISODE THAT OCCURRED IN (b) (6) THAT COINCIDED WITH THE USE OF BABY TEETHING TABLETS. NOW SHE IS CALLING BECAUSE THE REPORTER HAS 2 YOUNGER CHILDREN (OTHER THAN THE ACTUAL PATIENT) AND SHE WANTS TO CONSIDER PURCHASING THE TEETHING TABLETS FOR THEM BUT HAS RECENTLY HEARD ABOUT SEIZURE RUMORS AND NOW MOTHER ALSO WONDERS IF THIS COULD HAVE BEEN RELATED TO HER CHILD'S SEIZURE IN (b) (6) THE BABY'S SEIZURES OCCURRED EARLY IN THE MORNING AND EACH EPISODE GOT PROGRESSIVELY WORSE. THE MOTHER TOOK HER BABY TO THE HOSPITAL AND THE BABY CONTINUED TO HAVE SEIZURES IN THE HOSPITAL. CHILD WAS HOSPITALIZED FOR 4 DAYS. MOTHER STATES THAT BABY WAS "PUKING" AND WENT TO HOSPITAL THE DAY BEFORE. BABY TOOK NAUSEA AND VOMITING MEDICINES. NEXT DAY SHE HAD SEIZURE. NAUSEA VOMITING MEDICINE IS UNKNOWN. BABY HAD JUST ONE DOSE. MOTHER WAS SICK AS WELL. MOTHER RECALLS THAT THE BABY DIDN'T FEEL TOO WARM AND STATES MAYBE 99 TO 100 DEGREES TEMPERATURE. BABY NOW HAS SEIZURE MEDICINE ON HAND – DIAZEPAM 5 MG SUPPOSITORIES AS NEEDED. NO SEIZURES SINCE ORIGINAL EPISODE. NO OTHER MEDICAL CONDITIONS. EEG – NORMAL. FOLLOW-UP 1 MONTH LATER WAS "NOTHING ELSE WRONG"; FOLLOW-UP IN 1 YEAR AND GO FROM THERE. NO KNOWN DRUG ALLERGIES. NO KNOWN ENVIRONMENTAL ALLERGIES. NO KNOWN FOOD ALLERGIES.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

JUL 16 2014

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/25/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY: DATE: JUL 18 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1551

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/25/14 BY: (b) (6)

JUL 17 2014

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 07-07-14

BY: Eric Bair DATE: 07-03-14

QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10314685-01-00-04

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0028-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-eight Adverse Events (AE) which also included twenty Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tables. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

6/26/14
Date

DSS
JUL 18 2014

JUL 17 2014

CC-0439-2014
AE-0251-2014
SAE# 165

Individual Case Safety Report

10314685-01-00-05

CaseID: 10314685

ADVERSE EVENT DATA FORM

AE #: 1551 **COMPLAINT #:** 2561

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

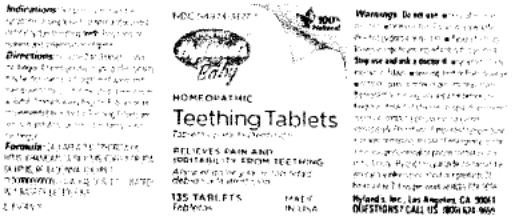
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

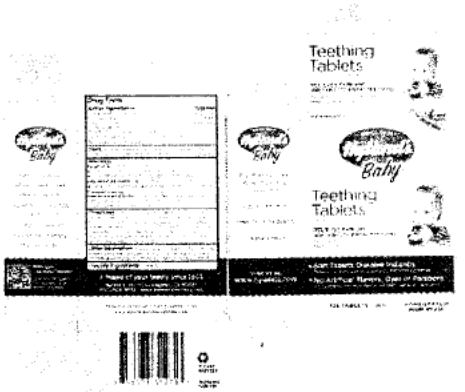
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS

JUL 18 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

JUL 17 2014

REVIEWED BY MANAGEMENT BY: DATE: 07-07-14

BY: Eric Baum DATE: 07-07-14

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

10359541-01-00-01

CaseID: 10359541

...iet Consumer Report

CDER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

...LUNTARY reporting of ...nts, product problems and product use errors

1/3

...Safety Information and Adverse Event Reporting Program

FDA USE ONLY

Triage unit sequence # 559308

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	9 Months (b) (6)	☐ Female ☑ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
12/25/2006	07/31/2014

5. **Describe Event, Problem or Product Use Error**

When my son, (b) (6) (BD (b) (6)) was an infant, we used Orajel and found that it didn't work quite well. I started using Hylands Teething Tablets, which seemed to help his teething pains. On (b) (6) (b) (6) he started experiencing seizures. He has used several different seizure medications, prescribed by several different doctors. He has undergone MRI, EEG, EKG and other medical testing. There is no neurological abnormalities. Doctors diagnosed his with Generalized Epilipsey with Feberile Seizures. (19 Febrile seizures, 13 Epiliptic Seizures.)

6. **Relevant Tests/Laboratory Data, Including Dates**

MRI- 2013 EEG- ...

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

Race:White

For additional information see B7 below.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*

#1 Name: teething tablets
Strength: Hylands Teething Tablets
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	Three times daily	Taken by mouth
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 4 months
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

CTU

3. **Manufacturer Name, City and State**

AUG - 1 2014

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	**Other #**	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
(b) (6)

DSS

AUG 01 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

... 2007, 2013 EKG- 2009, 2011, 2014

Individual Case Safety Report

10359541-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Medical Conditions: Seizures

Allergies: Omnicef, Fat protein in whole milk.

Important Information:

RX Meds: Keppra 150mg Adderol 15mg Clonodine .1mg

OTC Meds:

Individual Case Safety Report

10359541-01-00-03

Individual Case Safety Report

CaseID: 10384035

10384035-01-00-01

For use by user-facilities, distributors and manufacturers MANDATORY reporting

OTC

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence

2. Age at Time of Event: 9 Months or Date of Birth:

3. Sex: ☐ Female ☑ Male

4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy)
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 04/00/2013 -- 06/00/2014

4. Date of This Report (mm/dd/yyyy): 07/25/2014

5. Describe Event or Problem

CHILD SUFFERING FROM SEIZURES SINCE APRIL 2013 DIAGNOSED AS FEBRILE IN ORIGIN. MOTHER STATES THAT OCCURRENCE OF SEIZURES COINCIDES WITH DOSING OF BABY TEETHING TABLETS. SINCE DISCONTINUING BABY TEETHING TABLETS CHILD HAS NOT HAD A SEIZURE IN THE PAST 1.5 MONTHS.

RECEIVED
AUG 12 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

MRI SHOWED HIPPOCAMPAL MALFORMATION
EEG NORMAL

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

HISTORY OF EAR INFECTIONS AND HAS TUBES PLACED IN THE EARS.

CHILD'S GRANDMOTHER HAD SEIZURES 40 YEARS AGO PRIOR TO BEING DIAGNOSED WITH CROHN'S DISEASE. CUSTOMER'S SISTER HAD A SEIZURE AT THE AGE OF 3 AS A RESULT OF AN ILLNESS THAT STARTS WITH THE LETTER R.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used

#1 UNKNOWN DOSE X 1 YEAR

#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)

#1

#2

4. Diagnosis for Use (Indication)

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1

#2

7. Exp. Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Unique Identifier (UDI) #

5. Operator of Device
☐ Health Professional
☐ Lay User/Patient
☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
AUG 13 2014

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)
(b) (6) USA

AUG 12 2014

Phone # (b) (6)

Email Address (b) (6)

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☑ Unk.

Individual Case Safety Report

CaseID: 10384035

10384035-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address:
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/23/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURES

9. Manufacturer Report Number: 54973 AE # 1554

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
AUG 13 2014

AUG 12 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report

CaseID: 10384035

10384035-01-00-03

COMPLAINT RECORD

COMPLAINT #: 2564

DATE OF COMPLAINT: 07/23/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: THREW AWAY BOTTLE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL: (b) (6)

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL BUT DID NOT RESPOND TO HYLAND'S E-MAIL: MESSAGE: I THOUGHT I WOULD SEND YOU A MEMO ABOUT MY CHILD...MY CHILD HAS BEEN SUFFERING FROM FEBRILE SEIZURES SINCE 04/13 – 9 MONTHS OLD. I CONTINUED TO GIVE HIM TEETHING TABLETS DURING HIS TEETHING ESP DURING THE MONTH OF JULY BECAUSE HE WAS TEETHING, WELL HE WAS HAD ABOUT 4 SEIZURES IN THAT MONTH. THEY KEPT SAYING IT WAS HIS EARS AND EAR INFECTIONS. IN SEPTEMBER WE GOT TUBES IN HIS EARS AFTER HE GOT SICK AGAIN AND HAD A SEIZURE THAT LAST ALMOST AN HOUR. HE STILL CONTINUED TO HAVE SEIZURES. WELL HE STARTED HAVING SEIZURES AGAIN IN APRIL. AND I KNOW I HADN'T BEEN PUSHING TEETHING TABLETS ON HIM AS MUCH PRIOR TO THAT CUZ HE REALLY WASN'T TEETHING MUCH....WELL HE ENDED UP HAVING TWO MORE SEIZURES IN MAY AND JUNE....BUT EACH TIME I REMEMBER GIVING HIM TEETHING TABLETS WITHIN 24 HOURS PRIOR TO. SO I DECIDED TO DO A TRIAL AND ERROR AND THROW AWAY THE BOTTLES...AND WE ARE A MONTH AND HALF FREE OF SEIZURES...AND HE IS NOW 2 YEARS OLD. I'M NOT SUING YOU IN ANY MEANS BUT I WILL CONTINUE TO WORK ON THIS TRIAL...IF HE HAS ANOTHER SEIZURE THEN I WILL CRASH MY THEORY BUT RIGHT NOW...I AM HAPPY NOT SEEING MEDICAL BILLS FOR EVERYTIME WE WERE GOING FOR THE SEIZURES. CHILD'S GRANDMOTHER HAD SEIZURES 40 YEARS AGO PRIOR TO BEING DIAGNOSED WITH CROHN'S DISEASE. CHILD'S AUNT HAD A SEIZURE AT THE AGE OF 3 AS A RESULT OF AN ILLNESS THAT STARTED WITH LETTER R. MRI SHOWED HIPPOCAMPAL MALFORMATION; EEG NORMAL.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 07/23/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1554

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 07/23/14 BY: EDYTA FRACKIEWICZ

DSS AUG 13 2014 AUG 12 2014

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 08-01-14

BY:

QA / QC DIRECTOR

DATE: 07-31-14

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VD1

10384035-01-00-04

STANDARD HOMEOPATHIC
THE USA SINCE 1903

Serious Adverse Event
SAE-0031-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-nine Adverse Events (AE) which also included twenty Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

7/31/14
Date

DSS
AUG 13 2014

AUG 12 2014

Individual Case Safety Report

CaseID: 10384035

10384035-01-00-05

Hyland's

)VERSE EVENT DATA FORM

AE #: 1554 COMPLAINT #: 2564

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

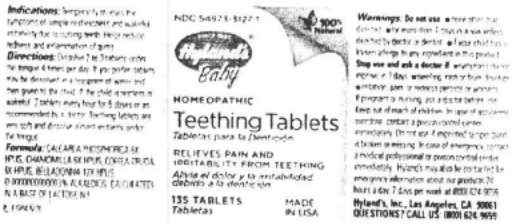
COUNTRY: USA ZIP CODE:

PHONE #:

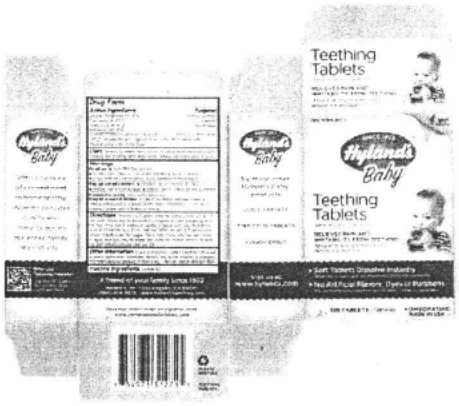
E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
AUG 13 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 08-01-14

BY: DATE: 07-31-14
QA / QC DIRECTOR

AUG 12 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CDER

CaseID: 10387468

10387468-01-00-01

HUMAN SERVICES
istration

OTC

Form Approved: OMB No. 0910-0291
Expiration Date: 6/30/2015
(See PRA Statement on preceding general information page

MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

CTU

AUG 14 2014

What kind of problem was it? *(Check all that apply)*

- [X] Were hurt or had a bad side effect *(including new or worsening symptoms)*
- [ ] Used a product incorrectly which could have or led to a problem
- [ ] Noticed a problem with the quality of the product
- [ ] Had problems after switching from one product maker to another maker

Did any of the following happen? *(Check all that apply)*

- [ ] Hospitalization – admitted or stayed longer
- [ ] Required help to prevent permanent harm *(for medical devices only)*
- [ ] Disability or health problem
- [ ] Birth defect
- [ ] Life-threatening
- [ ] Death *(include date)*: _____
- [X] Other serious/important medical incident *(Please describe below)*

seizure activity

Date the problem occurred *(mm/dd/yyyy)*

5-8-14

Tell us what happened and how it happened. *(Include as many details as possible)*

on (b) (6) (b) (6) was sleeping in her swing and started screaming & shaking. I had to shake her to wake up then she continue

List any relevant tests or laboratory data if you know them. *(Include dates)*

on (b) (6) they took blood work, and X ray on her belly. then they refered us to a nurologist

For a problem with a product, including:

- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

Go to Section B

For a problem with a medical device, including:

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as pregnancy tests, hearing aids, and breast pumps

DSS

Go to Section C

AUG 14 2014

For more information, visit *http://www.fda.gov/MedWatch*

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

10387468-01-00-02

CaseID: 10387468

560737

Section B – About the Products

r package *(include as many names as you see)*

Hyland baby teething tablets

Name of the company that makes the product

Hyland

Expiration date *(mm/dd/yyyy)*	Lot number	NDC number
	A22514	

Strength *(for example, 250 mg per 500 mL or 1 g)*	Quantity *(for example, 2 puffs, or 1 teaspoon, etc.)*	Frequency *(for example, twice daily or at bedtime)*	How was it taken or used *(for example, by mouth, by injection, or on the skin)?*
	2 to 3 tablets	every 6 hours	under the tongue

Date the person first started taking or using the product *(mm/dd/yyyy)*: 4/6/2014

Date the person stopped taking or using the product *(mm/dd/yyyy)*: 5/28/2014

Why was the person using the product *(such as, what condition was it supposed to treat?)*

teething

Did the problem stop after the person reduced the dose or stopped taking or using the product? ☒ Yes ☐ No

Did the problem return if the person started taking or using the product again? ☐ Yes ☐ No ☒ Didn't restart

Do you still have the product in case we need to evaluate it? *(Do not send the product to FDA. We will contact you directly if we need it.)* ☒ Yes ☐ No

➡ *Go to Section D (Skip Section C)*

Section C – About the Medical Device

Name of medical device

Name of the company that makes the medical device

Other identifying information *(The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)*

Was someone operating the medical device when the problem occurred? ☐ Yes ☐ No

If yes, who was using it?

☐ The person who had the problem

☐ A health professional *(such as a doctor, nurse, or aide)*

☐ Someone else *(Please explain who)*

DSS

AUG 14 2014

For implanted medical devices ONLY *(such as pacemakers, breast implants, etc.)*

Date the implant was put in *(mm/dd/yyyy)*

Date the implant was taken out *(If relevant) (mm/dd/yyyy)*

➡ *Go to Section D*

5063B CaseID: 10387468

Section D – About the Person Who Had the Problem

Person's Initials	Sex	Age *(at time the problem occurred)* or Birth Date	Weight *(Specify lbs or kg)*	Race
(b) (6)	☒ Female ☐ Male	(b) (6)	12 lbs	white

Individual Case Safety Report

10387468-01-00-03

blood pressure, cancer, heart disease, or others)

Please list all allergies *(such as to drugs, foods, pollen, or others).*

List any other important information about the person *(such as smoking, pregnancy, alcohol use, etc.)*

List all current prescription medications and medical devices being used.

Continuation Page

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

tylenol baby

Continuation Page

Go to Section E

Section E – About the Person Filling Out This Form

We will contact you only if we need additional information. Your name will not be given out to the public.

Last name	First name
(b) (6)	(b) (6)

Number/Street	City and State/Province
(b) (6)	(b) (6)

Country	ZIP or Postal code
USA	(b) (6)

Telephone number	Email address	Today's date *(mm/dd/yyyy)*
(b) (6)		7/2/14

Did you report this problem to the company that makes the product (the manufacturer)?	May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product?
☐ Yes ☒ No	☒ Yes ☐ No

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA. Mail or fax the form to:

Mail:	Fax:
MedWatch Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	1-800-332-0178 (toll-free)

DSS
AUG 14 2014

Thank you for helping us protect the public health.

For more information, visit *http://www.fda.gov/MedWatch*	**Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

[redacted]

d how it happened. *(Include as many details as possible)*

to shave and scream for about 1/5 minutes she had no strength to stand or sit up and thats not normal for her. I called the Dr, he was very conserned

[redacted]

CONTINUED ENTRY FOR: List any relevant tests or laboratory data if you know them. *(Include dates)*

[redacted]

CONTINUED ENTRY FOR: List all current prescription medications and medical devices being used.

[redacted]

CONTINUED ENTRY FOR: List all over-the-counter medications and any vitamins, minerals, and herbal remedies being used.

DSS

AUG 14 2014

[redacted]

560731

10387468-01-00-05

(b) (6)

Emergency Department

(b) (6)

Emergency Department Visit Summary

This discharge plan has been designed to give you information that you will need to care for yourself after you leave the hospital.

PLEASE TAKE THIS FORM TO YOUR FOLLOW-UP APPOINTMENT WITH YOUR DOCTOR.

Patient Information

Name (MRN)	Sex	Age	DOB	Dept Info
(b) (6)	**Female**	**0.41**	(b) (6)	(b) (6)

You were seen by

(b) (6) MD

Diagnoses this visit

Your diagnosis was EPISODE OF SHAKING .

Allergies as of (b) (6)

No Known Allergies (drug, envir, food or latex)

Take only the medications listed below. DO NOT use any other medications without first checking with your doctor. Contact your doctor to confirm your home medications.

Medication List

As of (b) (6) 6:26 AM

Notice

You have not been prescribed any medications.

All Patients:
An up-to-date medication list is very important to your safe care. Bring your list to all healthcare appointments. Carry it with you at all times in case of emergency. Update your list whenever you start a new medication, change the dose of a current medication, or stop a prior medication. Remember to include over-the-counter medications and supplements such as vitamins and herbs.

DSS
AUG 14 2014

ED Disposition

Discharge

Summary of Tests and Procedures

Return to the Emergency Department or notify your primary care physician for symptoms that persist or worsen.
Please return to the Emergency Department for any concerns if your primary care physician cannot be

vider, call the (b) (6) referral number at (b) (6)

Laboratory Tests Pending Results

Order	Current Status
Blood culture (PEDS ONLY)	In process

Follow-up Information

Follow up with (b) (6) **Division of Child Neurology. (New onset seizure clinic)**

Contact information:

(b) (6)

Discharge Instructions

Give her prune or pear juice if she doesn't have a bowel movement.

Call the new onset seizure clinic above for an appointment for further evaluation.

Patient/Parent-Guardian Signature:_____ **Date:**_____

(b) (6)

(b) (6)

CaseID: 10390459

Individual Case Safety Report

10390459-02-00-01

...se by user-facilities, ...ributors and manufacturers ...IDATORY reporting

OTC

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	33 Years	☑ Female ☐ Male	lbs / kgs
In confidence	or Date of Birth:		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
07/28/2014	08/01/2014

5. Describe Event or Problem

WOMAN HAD SEVER PAIN FROM A DENTAL EXTRACTION AND 5 DAYS LATER RETURNED TO THE DENTIST WHO RECOMMENDED TEETHING TABLETS ALONG WITH PAIN MEDICATION (HYDROCODONE ACETAMINOPHEN, QUALITEST NORCO; ALEVE, NEPROXEN ALTERNATELY). AFTER TAKING 3 TEETHING TABLETS SHE "FELT SHAKY" WITH HER "HEART BEATING TOO FAST", "EDGY, LIKE SOMETHING WAS WRONG, LIKE AN ALLERGY". SHE EXPERIENCED FEELING NAUSEA, NUMBNESS AND TINGLING IN HER NOSE AND HANDS. WHILE WATCHING TV SHE CLOSED HER EYES AND ACCORDING TO HER BOYFRIEND WAS SHAKING. HE CALLED HER NAME AND SHE WAS NOT AWARE OF WHAT WAS GOING ON AS THOUGH SHE HAD A "BLACKOUT" FOR A FEW SECONDS. SHE THOUGHT IT WAS AN ALLERGIC REACTION AND WENT TO URGENT CARE WHERE THEY DID A CT SCAN, MRI, EKG. PATIENT DESCRIBED HER PAIN AS 10 / 10. URGENT CARE ASSESSED HER SYMPTOMS AS "MINOR SEIZURE" AND SENT HER TO EMERGENCY TO ATTEND TO THE DENTAL PAIN. IN THE PAST FEW MONTHS SHE HAS USED HYLAND'S BLADDER IRRITATION, EARACHE DROPS, AND VAGINITIS WITH NO ADVERSE SYMPTOMS. SHE HAS BEEN TO THE EMERGENCY 3 TIMES BECAUSE OF PAIN, ONCE AFTER THE "SEIZURE", AND TWICE SINCE DUE TO EXTREME DENTAL PAIN.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

CT SCAN BECAUSE OF SINUS PAIN FROM EXTRACTED TOOTH (#11) -- NORMAL
EKG BECAUSE OF HIGH HEART RATE.
"FLUIDS WERE OFF DUE TO ..."
MRI WAS CLEAR

Received SEP 04 2014 CDR

Received SEP 03 2014 CDR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

HISTORY OF VERTIGO 5 YEARS AGO AND DIZZINESS BUT NEVER A SEIZURE. NO FAMILY HISTORY OF SEIZURES. ASTHMA CONTROLLED SINCE CHILDHOOD, INHALER FOR EMERGENCIES; ANAPHYLACTIC ALLERGIES -- SYMPTOMS THAT MAY OCCUR INCLULDE: COUGH UNCONTROLLED, HIVES IN BACK OF THROAT, CLOSED THROAT, CAN'T BREATHE, USES ADOREX OR BENADRYL, EPIPEN. PRE-EXISTING CONDITIONS: FIBROMYALGIA, CHRONIC NAUSEA, ESOPHAGITIS, GUTD, VULVODYNIA, IBS WITH DIARRHEA

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 3 TABLETS ONCE ORALLY	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A22114	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

NICONE, CLARITIN, COMPAZINE, AMITRIPTYLINE, CIMETIDINE, PRILOSEC, FLUNISOLIDE, TOLTERODINE-TARTRATE. ALSO TAKEN ACTIVATED CHARCOAL TABLETS. HYDROCODONE ACETAMINOPHEN, QUALITEST NORCO, ALEVE, NEPROXEN ALTERNATELY. ALSO

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)* SEP 05 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

SEP 04 2014

Phone # (b) (6) | Email Address (b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

Individual Case Safety Report

CaseID: 10390459

10390459-02-00-02

FDA USE ONLY

F.

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address:
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/30/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #:

7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☑ Follow-up # 1

8. Adverse Event Term(s): SEIZURES

9. Manufacturer Report Number: 54973 AE # 1555

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
SEP 05 2014

SEP 04 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report

10390459-02-00-03

ATION PAGE)
user-facilities,
ors, and manufacturers
TORY reporting

FORM FDA 3500A (2/13) (continued)

Back to Item B.5

B.5. **Describe Event or Problem** *(continued)*

Back to Item B.6

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

Back to Item B.7

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

PCOS (POLYCYSTIC OVARIES), BIPOLAR.

ALLERGIES: "ALMOST EVERYTHING": BEE AND WASP STINGS, SHELLFISH, CHLORINE, FLUORIDE, DOMESTICONE (SILICONE), MEDICATIONS: IBUPROFEN, SOMA, RANITIDINE, FERROUS SULPHATE, Q-VAR (INHALER), CAYENNE HORSERADISH, SEASONAL TREES, POLLEN, MOLD, PETS.

Back to Item C.10 Back to Item D.11

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

PERCOCET, DILAUDID, DEMEROL.

DSS
SEP 05 2014

Other Remarks

SEP 04 2014

Individual Case Safety Report

10390459-02-00-04

OMER COMPLAINT RECORD

C 10390459

COMPLAINT #: 2565

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 07/30/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: A22114

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: WOMAN HAD SEVERE PAIN FROM A DENTAL EXTRACTION AND 5 DAYS LATER RETURNED TO THE DENTIST WHO RECOMMENDED TEETHING TABLETS ALONG WITH PAIN MEDICATION (HYDROCODONE ACETAMINOPHEN, QUALITEST NORCO; ALEVE, NEPROXEN ALTERNATELY). AFTER TAKING 3 TEETHING TABLETS SHE "FELT SHAKY" WITH HER "HEART BEATING TOO FAST", "EDGY, LIKE SOMETHING WAS WRONG, LIKE AN ALLERGY". SHE EXPERIENCED FEELING NAUSEA, NUMBNESS AND TINGLING IN HER NOSE AND HANDS. WHILE WATCHING TV SHE CLOSED HER EYES AND ACCORDING TO HER BOYFRIEND WAS SHAKING. HE CALLED HER NAME AND SHE WAS NOT AWARE OF WHAT WAS GOING ON AS THOUGH SHE HAD A "BLACKOUT" FOR A FEW SECONDS. SHE THOUGHT IT WAS AN ALLERGIC REACTION AND WENT TO URGENT CARE WHERE THEY DID A CT SCAN, MRI, EKG. MRI WAS CLEAR. CT SCAN WAS FOR THE PAIN SHE WAS HAVING IN HER SINUS AREA THAT CORRESPONDED TO THE AREA OF HER TOOTH EXTRACTION. IT WAS "INCONCLUSIVE". SHE HAS BEEN ON DIFFERENT PAIN MEDICATIONS SINCE THE EXTRACTION 5 DAYS PREVIOUSLY AND DESCRIBES HER PAIN AS 10/10. THERE IS A HISTORY OF VERTIGO 5 YEARS AGO AND DIZZINESS BUT NEVER A SEIZURE. (NO FAMILY HISTORY OF SEIZURES). URGENT CARE ASSESSED HER SYMPTOMS AS "MINOR SEIZURE" AND SENT HER TO EMERGENCY TO ATTEND TO THE DENTAL PAIN. IN THE PAST FEW MONTHS SHE HAS USED HYLAND'S BLADDER IRRITATION, EARACHE DROPS AND VAGINITIS WITH NO ADVERSE SYMPTOMS. SHE HAS BEEN TO THE EMERGENCY 3 TIMES BECAUSE OF PAIN, ONCE AFTER THE "SEIZURE", AND TWICE SINCE DUE TO EXTREME DENTAL PAIN. RECENTLY SHE HAS BEEN ON PERCOCET, DILAUDID, DEMEROL NONE OF WHICH IS "TOUCHING THE PAIN" (OF THE TOOTH EXTRACTION).

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 07/30/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

MAILED REFUND CHECK # 511715 TOTALING $ 7.00.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6) DATE: 08/12/14

DSS
SEP 05 2014

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1555

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 07/30/14 BY: TUTTI GOULD

SECTION V:

SEP 04 2014

REVIEWED BY MANAGEMENT BY: RWdH DATE: 08-21-14

BY: Eric Bain QA / QC DIRECTOR DATE: 08-21-14

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

CaseID: 10390459

Individual Case Safety Report

10390459-02-00-05

Mailed on 08/12/14
EC 0534-2014
SAE-0032-2014

July 31, 2014

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of $7.00. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach
President

Enc: Refund Check - $7.00

DSS
SEP 05 2014

SEP 04 2014

Standard Homeopathic Company • Setting the Standard in Homeopathy, Since 1903
210 West 131st Street • P.O. Box 61067 • Los Angeles, CA 90061 • (310) 768-0700 • fax (310) 516-8579

CaseID: 10390459

Individual Case Safety Report

10390459-02-00-07

COMPLAINT RECORD

Hyland's

mailed 08/07/14

Ticket# 7808 1145 0005 0169 6929

COMPLAINT #: 2565

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 07/30/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: A22114

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: WOMAN HAD SEVERE PAIN FROM A DENTAL EXTRACTION AND 5 DAYS LATER RETURNED TO THE DENTIST WHO RECOMMENDED TEETHING TABLETS ALONG WITH PAIN MEDICATION (HYDROCODONE ACETAMINOPHEN, QUALITEST NORCO; ALEVE, NEPROXEN ALTERNATELY). AFTER TAKING 3 TEETHING TABLETS SHE "FELT SHAKY" WITH HER "HEART BEATING TOO FAST", "EDGY, LIKE SOMETHING WAS WRONG, LIKE AN ALLERGY". SHE EXPERIENCED FEELING NAUSEA, NUMBNESS AND TINGLING IN HER NOSE AND HANDS. WHILE WATCHING TV SHE CLOSED HER EYES AND ACCORDING TO HER BOYFRIEND WAS SHAKING. HE CALLED HER NAME AND SHE WAS NOT AWARE OF WHAT WAS GOING ON AS THOUGH SHE HAD A "BLACKOUT" FOR A FEW SECONDS. SHE THOUGHT IT WAS AN ALLERGIC REACTION AND WENT TO URGENT CARE WHERE THEY DID A CT SCAN, MRI, EKG. MRI WAS CLEAR. CT SCAN WAS FOR THE PAIN SHE WAS HAVING IN HER SINUS AREA THAT CORRESPONDED TO THE AREA OF HER TOOTH EXTRACTION. IT WAS "INCONCLUSIVE". SHE HAS BEEN ON DIFFERENT PAIN MEDICATIONS SINCE THE EXTRACTION 5 DAYS PREVIOUSLY AND DESCRIBES HER PAIN AS 10/10. THERE IS A HISTORY OF VERTIGO 5 YEARS AGO AND DIZZINESS BUT NEVER A SEIZURE. (NO FAMILY HISTORY OF SEIZURES). URGENT CARE ASSESSED HER SYMPTOMS AS "MINOR SEIZURE" AND SENT HER TO EMERGENCY TO ATTEND TO THE DENTAL PAIN. IN THE PAST FEW MONTHS SHE HAS USED HYLAND'S BLADDER IRRITATION, EARACHE DROPS AND VAGINITIS WITH NO ADVERSE SYMPTOMS. SHE HAS BEEN TO THE EMERGENCY 3 TIMES BECAUSE OF PAIN, ONCE AFTER THE "SEIZURE", AND TWICE SINCE DUE TO EXTREME DENTAL PAIN. RECENTLY SHE HAS BEEN ON PERCOCET, DILAUDID, DEMEROL NONE OF WHICH IS "TOUCHING THE PAIN" (OF THE TOOTH EXTRACTION).

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 07/30/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS
SEP 05 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1555

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 07/30/14 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 08-06-14

BY: Eric Baum
QA / QC DIRECTOR

DATE: 08-06-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

SEP 04 2014

Individual Case Safety Report

10390459-02-00-08

STANDARD HOMEOPATHIC
IN THE USA SINCE 1903

...ous Adverse Event
SAE-0032-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A22114, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A22114 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A22114. The Baby Teething bulk lot # 122944 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured two other complaints (CC-0332-2014 & CC-0456-2014) have been received for Hyland's Baby Teething Tablets lot # A22114. The complaints were reviewed and they do not appear to be related. We will continue to monitor our reported incidents for potential trends. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A22114.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

8/6/2014
Date

DSS
SEP 0 5 2014

SEP 04 2014

CC-0418-2014
AE-0235-2014

Individual Case Safety Report

CaseID: 10390459

10390459-02-00-09

Hyland's

SE EVENT DATA FORM

AE #: 1555 **COMPLAINT #:** 2565

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

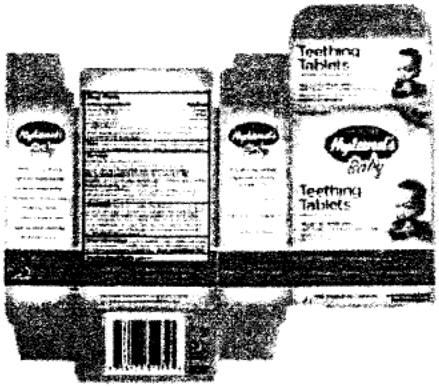
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS
SEP 0 5 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 08-06-14 SEP 04 2014

BY: Eric Baum DATE: 08-06-14
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

10395246-01-00-01

OTC CaseID: 10395246

CDER

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

...Y reporting of
...uct problems and
...e errors

FDA USE ONLY
Triage unit sequence # 561168

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	6 months.	☐ Female ☒ Male	___ lb or 9 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☒ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)* ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ___ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☒ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
7/17/2014	8/5/2014

5. Describe Event, Problem or Product Use Error

6month old male with fussiness which mother attributed to teething. Mother purchased Orajel at local Family Dollar and "coated his whole mouth" at 1145pm on 7/16/14. Mom awoke to feed child at 530AM, gave bottle, 30 min later child awoke crying, whole body stiffened and child made a runny mouth sound. 2 hours later, child again awakened + seemed to have difficulty breathing. Mother concerned

6. ~~Relevant Tests/Laboratory Data, Including Dates~~

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
for seizure
NICDA
Born full term

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☒ Yes ☐ No ☐ Returned to Manufacturer on: ___ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: orajel "Teething Pain Medicine"
Strength: Benzocaine 7.5% 3.5g tube.
Manufacturer: Church+Dwight
#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 7/16/2014	#1 ☒ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply
4. Diagnosis or Reason for Use *(Indication)*	8. Event Reappeared After Reintroduction?
#1 perpanent - teething	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name: CTU — 2b. Procode

3. Manufacturer Name, City and State
AUG 19 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)* — 7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

DSS AUG 19 2014

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
none

G. REPORTER *(See confidentiality section on back)*

1. Name and (b) (6)
Name:
Address:
City:

Phone # (b) (6) — E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☒ Yes ☐ No	physician	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☒

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

note:

Per "http://www.fda.gov/Drugs/DrugSafety/ucm402240.htm

[H: Lidocaine containing topical medications]

"Is NOT approved by FDA to treat teething pain" but

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

tube from which mother got medication clearly states name of med as. "Orajel Teething Pain Medicine"

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

F. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)* *(continued)*

Individual Case Safety Report

10402276-01-00-01

CaseID: 10402276

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

use by user-facilities,
istributors and manufacturers
ANDATORY reporting

Page 1 of 6

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	ADULT	☑ Female ☐ Male	lbs / kgs
In confidence	Date of Birth:		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
UNKNOWN	08/09/2014

5. Describe Event or Problem

SHE EXPERIENCED A SEIZURE AFTER TAKING 3 TABLETS OF OUR HYLAND'S TEETHING TABLETS. THINGS HAVE SETTLED DOWN SOME, BUT SHE STILL HAS A REALLY DIZZY / SHAKY FEELING.

Received
AUG 19 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

PATIENT HAS HAD THE INGREDIENTS CONTAINED IN OUR PRODUCTS IN OTHER FORMS, SO SHE KNOWS IT WAS NOT AN ALLERGIC REACTION.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2 HYLAND'S TEETHING TABELTS

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 3 TABLETS ONCE	#1
#2 3 TABLETS ONCE	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 TEMP RELIEF TEETHING PAIN	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1 // 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Unique Identifier (UDI) #	☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

AUG 20 2014

Phone #	Email Address (b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

AUG 19 2014

Individual Case Safety Report

CaseID: 10402276

10402276-01-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | 5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)* | 7. Type of Report ☐ Initial ☐ Follow-up # ____ | 8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device | 10. Event Problem Codes *(Refer to coding manual)* Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/28/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURE, DIZZY, SHAKY

9. Manufacturer Report Number: 54973 AE # 1556

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
AUG 20 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

AUG 19 2014

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's 10402276

SECTION I: COMPLAINT

COMPLAINT #: 2566

TAKEN BY: CATHERINE DOW
DATE OF COMPLAINT: 07/28/2014

PRODUCT: HYLAND'S BABY TEETHING TABLETS OR HYLAND'S TEETHING TABLETS
ITEM CODE: BTET TEET

SIZE: UNKNOWN UNKNOWN
LOT NO.: UNKNOWN UNKNOWN

REPORTER: (b) (6)

ADDRESS:

CITY:

COUNTRY: USA

PHONE #:

E-MAIL: (b) (6)

Individual Case Safety Report

10402276-01-00-03

NATURE OF COMPLAINT: SHE EXPERIENCED A SEIZURE AFTER TAKING TEETHING TABLETS. I TOOK THREE TABLETS ONCE. THINGS HAVE SETTLED DOWN SOME, BUT I STILL HAVE A REALLY DIZZY / SHAKY FEELING. HAS TAKEN ALL OF THE INGREDIENTS CONTAINED IN THIS PRODUCT IN OTHER FORMS, SO SHE KNOWS IT WAS NOT AN ALLERGIC REACTION.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: See attached PM 8/11/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 07/28/2014

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: CATHERINE DOW

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1556

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 07/28/2014. BY: CATHERINE DOW

DSS
AUG 20 2014

SECTION V:

REVIEWED BY MANAGEMENT BY: RWelch DATE: 08-11-14

BY: Eric Baum DATE: 08-11-14
QA / QC DIRECTOR

cc: QA / QC, Packaging, Production, Shipping / Receiving

AUG 19 2014

Form #VD

10402276-01-00-04

STANDARD HOMEOPATHIC
IN THE USA SINCE 1903

rious Adverse Event
SAE-0033-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) and Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-three Adverse Events (AE) which also included twenty-one Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). There have been three Adverse Event (AE) Reports and two Serious Adverse Events (SAE) reported for the Teething Tablets (TEET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq^{(b)}_{(4)}$ ppm.

Conclusion:

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

8/11/2014
Date

DSS
AUG 20 2014

AUG 19 2014

Individual Case Safety Report

10402276-01-00-05

ID: 10402276

ERSE EVENT DATA FORM

AE #: 1556 **COMPLAINT #:** 2566

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

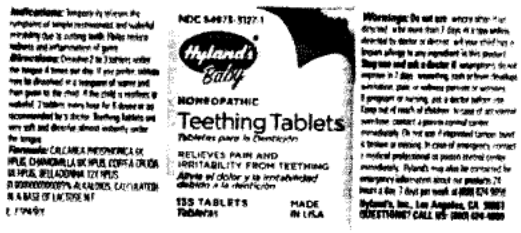
COUNTRY: USA ZIP CODE:

PHONE #:

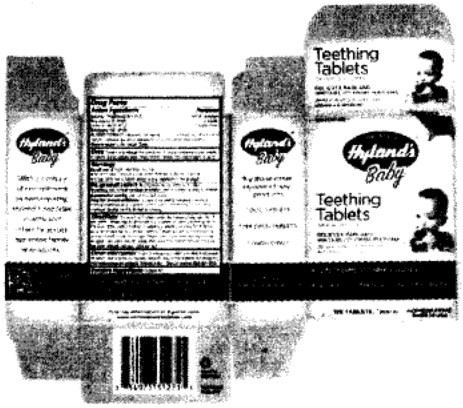
E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
AUG 20 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 08-11-14

BY: QA / QC DIRECTOR DATE: 08-11-14

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

AUG 19 2014

STANDARD
Individual Case Safety Report

10402276-01-00-06

ID:®10402276

ERSE EVENT DATA FORM

AE #: 1556 **COMPLAINT #:** 2566

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

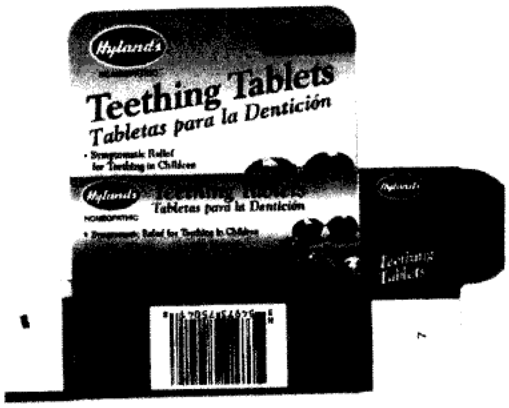
PHONE #:

E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
AUG 20 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 08-11-14

BY: ~~N/A~~ QA / QC DIRECTOR DATE: 08-11-14

EJB
08-11-14

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

AUG 19 2014

Individual Case Safety Report

10412341-01-00-01

OTC CaseID: 10412341

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

user-facilities,
ors and manufacturers
TORY reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

FORM FDA 3500A (2/13) Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) in confidence	2. Age at Time of Event: 4 Months or Date of Birth:	3. Sex ☑ Female ☐ Male	4. Weight ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
08/03/2014	08/10/2014

5. Describe Event or Problem

4 MONTH OLD BABY WAS GIVEN 1 BABY TEETHING TABLET DISSOLVED IN BABY SIZED SYRINGEFUL OF WATER AND STOPPED BREATHING. HER EYES WERE LARGE, AND HER BODY WAS LIMP. MOTHER HAD TO HIT HER ON THE BACK TO GET HER BREATHING AGAIN; THE BABY BEGAN TO BREATHE NORMALLY. FATHER RECEIVED A CALL FROM A MEDICAL DOCTOR WHILE WE WERE ON THE LINE.

AUG 2 2 2014

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD ALSO TAKES MEDICATIONS FOR ACID REFLUX AND COLIC

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1TAB DISSOLVED SYRINGE	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A22314	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

DSS
AUG 25 20

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of ev*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

AUG 22 2014

Phone # (b) (6)	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

10412341-01-00-02

FDA USE ONLY

1. Check One	2. UF/Importer Report Number
☐ User Facility ☐ Importer	

3. User Facility or Importer Name/Address

4. Contact Person	5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)	7. Type of Report	8. Date of This Report (mm/dd/yyyy)
	☐ Initial ☐ Follow-up # ____	

9. Approximate Age of Device	10. Event Problem Codes (Refer to coding manual)
	Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___

11. Report Sent to FDA?	12. Location Where Event Occurred
☐ Yes ____ (mm/dd/yyyy) ☐ No	☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No	

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)	2. Phone Number
Name: EDYTA FRACKIEWICZ Address: HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061 Email Address: STANDARD@HYLANDS.COM	310-768-0700

4. Date Received by Manufacturer (mm/dd/yyyy)	5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #	

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

3. Report Source (Check all that apply)
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

9. Manufacturer Report Number	8. Adverse Event Term(s)
54973 AE # 1558	STOPPED BREATHING

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event	2. If Follow-up, What Type?
☐ Death ☐ Serious Injury ☐ Malfunction	☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____	4. Device Manufacture Date (mm/yyyy) ____ 5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes (Refer to coding manual)
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type	8. Usage of Device
☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____	☐ Initial Use of Device ☐ Reuse ☐ Unknown 9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
AUG 25 2014

AUG 22 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report

10412341-01-00-03

PLAINT RECORD

Case No. 10412341

COMPLAINT #: 2568

DATE OF COMPLAINT: 08/03/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A22314

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: 4 MONTH OLD BABY WAS GIVEN 1 BABY TEETHING TABLET DISSOLVED IN BABY SIZED SYRINGEFUL OF WATER AND STOPPED BREATHING. HER EYES WENT LARGE, AND HER BODY LIMP. MOTHER HAD TO HIT HER ON THE BACK TO GET HER BREATHING AGAIN; THE BABY BEGAN TO BREATHE NORMALLY. FATHER RECEIVED A CALL FROM A MEDICAL DOCTOR WHILE WE WERE ON THE LINE. CHILD ALSO TAKES MEDICATION FOR ACID REFLUX AND COLIC.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 08/03/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS
AUG 25 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1558

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/03/14 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 08-15-14

BY:
QA / QC DIRECTOR

DATE: 08-15-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

AUG 22 2014

FORM VD1

VDARD ATHIC
BA SINCE 1903

Serious Adverse Event
SAE-0034-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A22314, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A22114 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A22314. The Baby Teething bulk lot # 122944 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # A22314. A search of the complaints related to lots packaged with the same bulk lot # 122944 was performed and three complaints were found (CC-0322-2014, CC-0456-2014 & CC-0534-2014/SAE-0032-2014). The complaints were reviewed and although a previous SAE has been reported related to this bulk lot the complaints do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A22314.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

8/13/14
Date

DSS
AUG 25 2014

AUG 22 2014

Individual Case Safety Report

10412341-01-00-05

ID: 10412341

E EVENT DATA FORM

AE #: 1558 COMPLAINT #: 2658

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

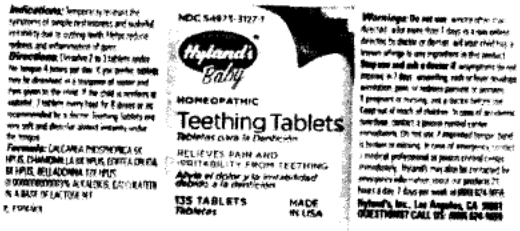
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

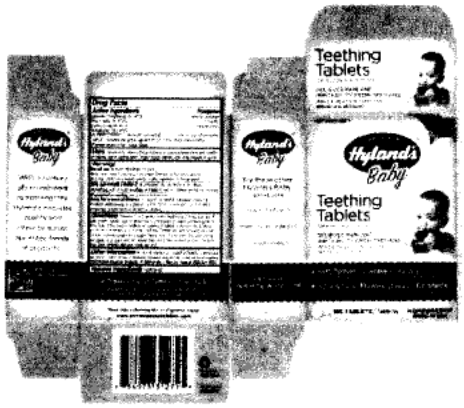
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE: DSS AUG 25 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt EE KW DATE: ~~08-14~~ 08-15-14

BY: Eric Bain QA / QC DIRECTOR DATE: 08-15-14

DISTRIBUTION: FDA ADVERSE EVENT FILE

AUG 22 2014

FORM SAE01

Individual Case Safety Report

CaseID: 10430246

10430246-01-00-01

Form Approved: OMB No. 0910-0291 Expires: 12/31/2011
Phase Forward FDA Facsimile Approval: 07/12/2006

care Holdings

Mfr report #	NSR_01615_2014
UF/Importer Report #	
	FDA Use Only

MEDWATCH

FORM FDA 3500A (6/10)

Page 1 of 3/4

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
Unknown In confidence	or 9 months Date of Birth:	☐ Female ☑ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/ malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: (mm/dd/yyyy)
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
	08/29/2014

5. Describe Event or Problem

Citation(s):
Owen ED Hughes J. Propranolol-related hypoglycaemic seizure in a 9-month-old infant: The importance of regular feeding throughout the course of treatment. British Journal of Dermatology 2014;171(S1):117.
MedDRA Version 16.1

Description of Event or Problem:
It was reported in the literature by healthcare professionals from the United Kingdom that a 9 month old twin male, with a history of irritability, received propranolol (route and formulation unknown), 2 mg/kg, daily (given in two divided doses), for rapidly enlarging haemangioma on the left pinna, in combination with unspecified teething gel (route, dose, and frequency unknown), for teething. No concomitant (cont.)

6. Relevant Tests/Laboratory Data, Including Da

Received
SEP 02 2014
CDR

(Tabularized lab data is appended.)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Relevant History:
Teething (Teething), Irritable (Irritable)

Concomitant disease(s):
Rapidly enlarging haemangioma on the left pinna (Haemangioma)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 PROPRANOLOL (Propranolol)
#2 Teething gel

2. Dose, Frequency & Route Used	3. Therapy Dates *(if unknown, give duration)* from/to (or best estimate)
#1 (2 mg/kg, (cont.)	#1 (Unknown (cont.)
#2 (DF)	#2 (Unknown)

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 Haemangioma	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 Teething	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*
NorthStar Healthcare Holdings, Joseph Mastronardy, Ph. D. Quality Regulatory Consultants, 1966 Anglers Cove, Vero Beach, FL 32963 USA

2. Phone Number: 434-326-1014

3. Report Source (Check all that apply)
☑ Foreign
☐ Study
☑ Literature
☐ Consumer
☑ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other: (cont.)

DSS
SEP 03 2014

4. Date Received by Manufacturer (mm/dd/yyyy)	5. (A)NDA # 78-213
08/22/2014	IND #
6. If IND, Give Protocol #	STN #
7. Type of Report (Check all that apply)	PMA/ 510(k) #
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up #	Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
9. Manufacturer Report Number: NSR_01615_2014	8. Adverse Event Term(s): Hypoglycaemic seizure (cont.)

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6) United Kingdom	

SEP 02 2014

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Unknown	☐ Yes ☐ No ☑ Unk.

B5. Describe event or problem (continued)

medications were reported. Therapy with propranolol was initiated on an unknown date and five months later, the patient experienced generalized seizure secondary to hypoglycaemia, difficult to rouse and floppy, developed jerky stiff movements before becoming pale and unresponsive, and was diagnosed with ketonic hypoglycaemia. Laboratory tests revealed capillary blood glucose: 1.1 mmol/L, serum glucose: 0.8 mmol/L, serum cortisol response: normal, urine: positive for ketones, temperature: 35.4 degrees Celsius, hypoglycaemia: < 3.5 mmol/L, and persistently low CBG in the early hours of the morning. Treatment included oral Dextrogel, buccal midazolam, fluids, antibiotics, antivirals, and warming. Subsequently, he made a complete recovery within 24 hours. Computed tomography head scan and metabolic study were normal. Therapy with propranolol was weaned down and stopped over seven days. On reassessment he had two further episodes of hypoglycaemia. He had no further seizures. The severity of his condition was presumed to be exacerbated by propranolol, with twice daily dosing and the use of teething gel as possible contributing factors. An additional bottle feed was sufficient to prevent any further episodes of hypoglycemia. The authors stated, "Informing parents about the risk of hypoglycemia in infants taking propranolol is important throughout the course of treatment. The need to avoid prolonged fasting and to continue regular feeds should be clearly emphasized. This is important not only in premature neonates during their first year of life but also in children up to the age of five years." No additional information was available at the time of this report.

Literature article is attached.

C2. Dose, frequency and route used for suspect product #1 (continuec)

daily [given in two divided doses])

C3. Therapy dates/durations used for suspect product #1 (continued)

until not continuing)

G3. Report source (continued)

Foreign: United Kingdom

G8. Adverse event terms (continued)

Drug interaction

B6. Lab Data

Panel	Test	Results	Units	Low Normal	High Normal	Normal?	Test Date
Laboratory test							
	Blood sugar	<3.5 (hypoglycemia)	mmol/L			Depressed	
	Capillary blood glucose	persistently low CBG				Depressed	
	Capillary blood glucose	1.1	mmol/L				
	Serum glucose	0.8	mmol/L				
	Urinalysis	positive for ketones					
Vital signs							
	Body temperature	35.4	degrees Celsius				

Owen and Hughes: Propranolol-related hypoglycaemic seizure in a 9-month old infant: the importance of regular feeding throughout the course of treatment. British Association of Dermatologists 2014 171 (Suppl. 1), pp 115-130.

Individual Case Safety Report

CaseID: 10436018

10436018-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...er-facilities, ...s and manufacturers ...RY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence

2. Age at Time of Event: 10 Months or Date of Birth:

3. Sex: [x] Female [ ] Male

4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death: ____ (mm/dd/yyyy)
- [ ] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [x] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 05/25/2014 -- 05/31/2014

4. Date of This Report (mm/dd/yyyy): 06/26/2014

5. Describe Event or Problem

THE WEEK OF USING THE TABLETS CHILD HAD SEIZURE TYPE SYMPTOMS - TENSING UP, SHAKING THAT LASTED 5 - 10 SECONDS AND OCCURRED ABOUT 10 TIMES OVER A PERIOD OF A WEEK. WENT TO THE EMERGENCY ROOM BUT SYMPTOMS WERE NOT OCCURING AT THE TIME. DOCTOR COULD NOT TELL IF THIS WAS SEIZURE BUT STATED IT COULD BE SEIZURE TYPE ACTIVITY. SINCE STOPPING BABY TEETHING TABLETS, THE CHILD HAS NOT HAD ANY SEIZURE TYPE SYMPTOMS.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

NONE

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

FATHER'S BROTHER HAS A HISTORY OF GRAND MAL SEIZURES.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used

#1 1-2 TABS BID-TID X 1WEEK

#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)

#1

#2

4. Diagnosis for Use (Indication)

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 [x] Yes [ ] No [ ] Doesn't Apply

#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #

#1 BI2113

#2

7. Exp. Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 [ ] Yes [ ] No [x] Doesn't Apply

#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: [ ] Health Professional [ ] Lay User/Patient [ ] Other:

Catalog # | Expiration Date (mm/dd/yyyy)

Serial # | Unique Identifier (UDI) #

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [ ] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA) [ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

DSS

SEP 05 2014

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address (b) (6)

Phone # (b) (6)

Email Address

2. Health Professional? [ ] Yes [x] No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [x] Unk.

SEP 04 2014

Individual Case Safety Report

CaseID: 10436018

10436018-01-00-02

of 5

FDA USE ONLY

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

11. Report Sent to FDA?

☐ Yes ____ *(mm/dd/yyyy)*

☐ No

12. Location Where Event Occurred

☐ Hospital ☐ Outpatient Diagnostic Facility

☐ Home ☐ Ambulatory Surgical Facility

☐ Nursing Home

☐ Outpatient Treatment Facility

☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?

☐ Yes ____ *(mm/dd/yyyy)*

☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*

☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/25/2014

5. (A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*

☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURE TYPE SYMPTOMS, SHAKING, TENSING

9. Manufacturer Report Number: 54973 AE # 1550

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event

☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?

☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?

☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?

☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

Method ____ - ____ - ____ - ____

Results ____ - ____ - ____ - ____

Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type

☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device

☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
SEP 05 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

SEP 04 2014

Individual Case Safety Report

10436018-01-00-03

INT RECORD mailed 7/3/14 article NO. 7008 1830 0004 8628 0515

10436018

COMPLAINT #: 2560

DATE OF COMPLAINT: 06/25/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET—T135

SIZE: 135 TABLETS

LOT NO.: B12113

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: WAS GIVING BABY TEETHING TABLETS 1 – 2 TABLETS TWO TIMES A DAY – THREE TIMES A DAY FOR 1 WEEK. THE WEEK OF (b) (6) THE WEEK OF USING THE TABLETS CHILD HAD SEIZURE TYPE SYMPTOMS – TENSING UP, SHAKING THAT LASTED 5 – 10 SECONDS – THIS HAPPENED ABOUT 10 TIMES OVER THE WEEK. WENT TO THE EMERGENCY ROOM BUT SYMPTOMS WERE NOT OCCURING AT THE TIME. DOCTOR COULD NOT TELL IF THIS WAS SEIZURE BUT STATED IT COULD BE SEIZURE TYPE ACTIVITY. ER DOCTOR DID NOT RUN TESTS AND HE SAID THAT IF SHE CONTINUES TO HAVE SYMPTOMS SHE SHOULD BE EVALUATED BY HER PRIMARY DOCTOR. SINCE STOPPING BABY TEETHING TABLETS, THE CHILD HAS NOT HAD ANY SEIZURE TYPE SYMPTOMS. FATHER EXPRESSED THAT HIS THEORY IS THAT MORE STUDIES NEED TO BE DONE ON THE TEETHING TABLETS. HE RECOMMENDS PUTTING KIDS IN A HOSPITAL SETTING AND GIVING THEM TEETHING TABLETS AND OBSERVING THEM. HE IS A CONCERNED PARENT AND IS NOT GOING TO SUE. FATHER'S BROTHER HAS A HISTORY OF GRAND MAL SEIZURES. WOULD LIKE A REFUND FOR 2 BOTTLES.

COMMENTS TO REPORTER: WILL SEND A REFUND. TOLD HIM THAT SOMETIMES A CHILD COULD BE SENSITIVE TO AN INGREDIENT IN THE BABY TEETHING TABLETS OR THE SYMPTOMS COULD BE DUE TO SOMETHING ELSE. PROVIDED INFORMATION ABOUT THE INGREDIENTS IN THE BABY TEETHING TABLETS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/25/2014

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1550

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/25/2014 BY: EDYTA FRACKIEWICZ

DSS SEP 05 2014

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 07-02-14

BY: QA / QC DIRECTOR DATE: 07-01-14

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

SEP 04 2014

10436018-01-00-04

'DARD
THIC
SINCE 1903

Serious Adverse Event
SAE-0027-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B12113, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B12113 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B12113. The Baby Teething bulk lot # 121015 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other customer complaint (CC-0091-2014) has been received for Hyland's Baby Teething Tablets lot # B12113. The complaints were reviewed and there does not appear to be a trend related to this lot. We will continue to monitor our reported incidents for potential trends. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B12113.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/26/14
Date

DSS
SEP 05 2014

CC-0438-2014
AE-0250-2014

SEP 04 2014

Individual Case Safety Report

CaseID: 10436018

10436018-01-00-05

Hyland's

EVENT DATA FORM

AE #: 1550 **COMPLAINT #:** 2560

SECTION I: **PATIENT INFORMATION** *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

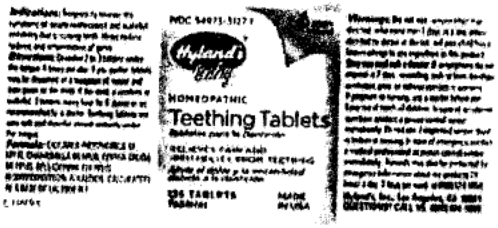
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
SEP 05 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 07-02-14

BY: QA / QC DIRECTOR DATE: 07-01-14

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

SEP 04 2014

Individual Case Safety Report

CaseID: 10436103

10436103-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

OTC

ser-facilities, rs and manufacturers DIY reporting

Mfr Report # 54973
UF/Importer Report #
FDA Use Only

FORM FDA 3500A (2/13)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: 6 Months or Date of Birth:	3. Sex ☐ Female ☑ Male	4. Weight ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/00/2014 -- 07/00/2014	08/18/2014

5. Describe Event or Problem

CALLER REPORTS THAT APPROXIMATELY ONE MONTH AGO, HE GAVE HIS 6 MONTH OLD SON BABY TEETHING TABLETS. HE CLAIMS THAT SOON AFTER, HIS SON HAD A SEIZURE. CALLER AND HIS GIRLFRIEND TOOK THEIR SON TO THE EMERGENCY ROOM AFTER THE EPISODE. THE CHILD WAS STABILIZED AND WAS RETURNED HOME. AFTER AN UNKNOWN AMOUNT OF TIME, CALLER GAVE HIS SON ANOTHER DOSE OF TEETHING TABLETS AND CLAIMS THAT HE HAD ANOTHER SEIZURE APPROXIMATELY 6 - 8 HOURS LATER.

08/18/114 FOLLOW-UP: SEIZURE DESCRIBED AS CHILD SPACING OUT, EYES SHIFTING, SHAKING, COULD NOT BREATHE, UNRESPONSIVE. CALLED 911 AND IN THE HOSPITAL THEY SAID CHILD LOOKED FINE AND SENT HIM HOME. CHILD STILL HAVING SEIZURES NOW.

Received
SEP 04 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

EEG AND MRI WERE NORMAL.

CHILD GIVEN KEPPRA BY HOSPITAL.

Received
SEP 03 2014
CDR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO PRE-EXISTING CONDITIONS. NO ALLERGIES OR ILLNESSES. NO FEVER. NO HISTORY OF SEIZURES IN FAMILY.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1 TABLET SL PRN X 1 MO	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

ORAJEL

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

DSS
SEP 05 2014

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

Phone # (b) (6)	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

SEP 04 2014

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 10436103

10436103-01-00-02

f 5

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual): Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061
Email Address
2. Phone Number: 310-768-0700
3. Report Source (Check all that apply): ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer (mm/dd/yyyy): 08/17/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report (Check all that apply): ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURES
9. Manufacturer Report Number: 54973 AE # 1559

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code:
4. Device Manufacture Date (mm/yyyy)
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes (Refer to coding manual): Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___ Method ___ - ___ - ___ - ___ Results ___ - ___ - ___ - ___ Conclusions ___ - ___ - ___ - ___
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
SEP 05 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

SEP 04 2014

Individual Case Safety Report

10436103-01-00-03

COMPLAINT RECORD

Case ID: 10436103

COMPLAINT #: 2569

DATE OF COMPLAINT: 08/17/2014

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABLETS

LOT NO.: REFUSES TO PROVIDE

REPORTER: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CALLER REPORTS THAT APPROXIMATELY ONE MONTH AGO, HE GAVE HIS 6 MONTH OLD SON BABY TEETHING TABLETS. HE CLAIMS THAT SOON AFTER, HIS SON HAD A SEIZURE. CALLER AND HIS GIRLFRIEND TOOK THEIR SON TO THE EMERGENCY ROOM SOON AFTERWARDS. THE CHILD WAS STABILIZED AND WAS RETURNED HOME. AFTER AN UNKNOWN AMOUNT OF TIME, CALLER GAVE HIS SON ANOTHER DOSE OF TEETHING TABLETS AND CLAIMS THAT HE HAD ANOTHER SEIZURE APPROXIMATELY 6 – 8 HOURS LATER. CALLER THREATENED LEGAL ACTION IF HE DID NOT HEAR FROM SOMEONE BY TOMORROW.

EDYTA FRACKIEWICZ FOLLOWED-UP: SPOKE WITH CUSTOMER ON 08/18/14. HE WAS USING ORAGEL AND THEN STARTED USING THE TEETHING TABLETS. CHILD STARTED SPACING OUT, THEN EYES STARTED SHIFTING, SHAKING, COULD NOT BREATHE, UNRESPONSIVE. CALLED 911 AND IN THE HOSPITAL THEY SAID CHILD LOOKED FINE AND SENT HIM HOME. EEG AND MRI WERE NORMAL. WANTS TO KNOW WHY BELLADONNA IS IN THE TABLETS. CHILD GOT KEPPRA IN THE HOSPITAL. HAD ANOTHER EPISODE WHERE HE TOOK A TEETHING TABLET AND HAD A SEIZURE. CHILD STILL HAVING SEIZURES NOW. HE CLAIMS NO FAMILY HISTORY OF SEIZURES. DOCTORS DON'T KNOW CAUSE OF SEIZURES BECAUSE ALL MEDICAL TESTS ARE NORMAL. GOING TO THE LAWYER TO PURSUE LEGAL ACTION AND WILL CALL THE FDA TODAY. OFFERED HIM A REFUND FOR THE TABLETS AND HE REFUSED. HE REFUSED TO PROVIDE THE LOT #.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 08/17/2014

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1559

DSS
SEP 05 2014

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/18/2014 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 08-20-14

BY: QA / QC DIRECTOR DATE: 08-20-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

SEP 04 2014

10436103-01-00-04

VDARD ATHIC SA SINCE 1903

Serious Adverse Event
SAE-0036-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-three Adverse Events (AE) which also included twenty-two Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels have been found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

8/19/14
Date

DSS
SEP 05 2014

SEP 04 2014

10436103-01-00-05

CaseID: 10436103

Hyland's

EVENT DATA FORM

AE #: 1559 COMPLAINT #: 2569

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

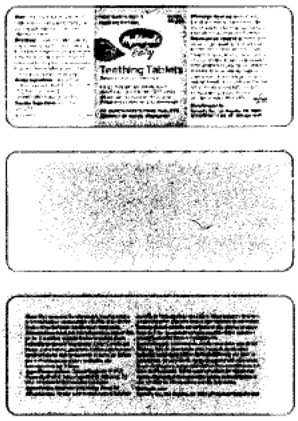
COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
SEP 0 5 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 08-20-14

BY: QA / QC DIRECTOR DATE: 08-20-14

SEP 04 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

10483550-01-00-01

CDER

CaseID: 10483550

ernet Consumer Report

VOLUNTARY reporting of events, product problems and product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	565958

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	2 Months (b) (6)	☐ Female ☑ Male	13 lb or kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)*
☑ Life-threatening
☑ Hospitalization - initial or prolonged
☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/26/2014	09/28/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hylands Best Teething Tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 1 1/2 months
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Doctor thought my son was teething early very fussy
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

CTU
SEP 29 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

DSS
SEP 29 2014

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

My son was a very fussy baby since birth in (b) (6) I took him to the dr around 1 month old and the doctor said he may be teething early and to try teething tablets. I started him on Hylands best teething tablets because my sister had given me a bottle for my 1 year old daughter not to long before that and she had never needed them. My son used them from 1 month old until 2 1/2 months old. When he was 2 1/2 months old I took him to (b) (6) (b) (6) Hospital in (b) (6) for a fever and seizure like symptoms. Once we arrived at the hospital he started having seizure like symptoms again. They did a spinal tap on him to test for menigitis but it came back with blood. They did the spinal tap two times and both times had blood so thy decided to do a catscan. It came back that my son had bleeding on the brain. He also had fractured ribs which I believe were caused when the spinal tap was perfomed. They said the only logical explanation for the bleeding on the brain was abusive trauma. I did not in any way shape or form harm my child. I have three children whom I love with all of my heart and would never ever hurt them. Now I'm hearing all these things about Hylands Best Teething tablets. That they can cause seizure like symptoms and bleeding on the brain and have actually read a few articles where they actually have caused severe issues with children and babies. Im desperately asking you to review this please and get back to me as soon a possible at (b) (6) I have emailed Hylands several times over the last week and have gotten absolutely no response, please please help me.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

My son had to hae brain surgery and had a shunt put in his head. He had to have several cat scans and several mri's. He had to stay in the hospital for a little over a week. He may have disbilities but it's to early to tell.

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:Black/African American
Medical Conditions: Gerds (Acid Reflux)

Allergies: none

Important Information:

RX Meds: Shunt in the head

OTC Meds: My aunt who has temporary custody was still giving him the tablets until i seen all issus and told her, Orajel couch n col medicine

10486049-01-00-01

CaseID: 10486049

nsumer Report

ARY reporting of CDER
roduct problems and
product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 5666102

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	6 Months (b) (6)	☐ Female ☑ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/10/2014	09/29/2014

5. **Describe Event, Problem or Product Use Error**
See page 2 for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**
See page 3 for complete text.

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
#1 Name: Hylands Best Teething tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 pills	As needed	Taken under the tongue
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 01/01/2014 - 07/01/2014	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply
4. Diagnosis or Reason for Use *(Indication)*	**8. Event Reappeared After Reintroduction?**
#1 Fussiness from teething	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

CTU

2. **Common Device Name**

SEP 30 2014

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	**Other #**	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
(b) (6)

DSS
30 2014

Phone #	E-mail
	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B.5. Describe Event or Problem *(continued)*

My son was being fussy. I assumed it was his teeth and gave him two of Hyland's Best teething tablets. We then went to lay down and I breastfed him. While nursing he tensed up and began to tremor and shake involuntarily. I placed my hand over his arm and it did not stop the shaking. He was having a seizure. After it stopped (about 30 second's later) I called his doctor. We went in for an exam and a few days later had an EKG on his brain waves. The tests did not find anything wrong. I believe now that it was due to the teething tablets.

Individual Case Safety Report

10486049-01-00-02

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

EKG was inconclusive

Individual Case Safety Report

10486049-01-00-03

B.7. Other Relevant History, Including Preexistin

ysfunction, etc.) (continued)

Race:American Indian/Alaskan Native
Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds:

10486072-01-00-01

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Y reporting of
uct problems and
product use errors

07 CaseID: 10486072

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 566093

The FDA Safety Information and
Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	2 Years (b) (6)	☐ Female ☑ Male	25 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☑ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/06/2012	09/29/2014

5. **Describe Event, Problem or Product Use Error**
See page 2 for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 2 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
#1 Name: teething tablets
Strength: unsure
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. **Dose or Amount** / **Frequency** / **Route**

	Dose or Amount	Frequency	Route
#1		--	--
#2			

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 09/30/2011 - 09/30/2012
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 Teething
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. **If Implanted, Give Date** *(mm/dd/yyyy)*

7. **If Explanted, Give Date** *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

CTU
SEP 30 2014
DSS
SEP 30 2014

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

I gave my son who is now 3 the teething tablets when he was a infant this recall really worries me when my son was two he began having seizures and almost died in my arms it lasted 15minutes the first tone and was hospitalized in icu. The second time lasted 11minutes was also hospitalized he also crys sometimes when he pees in his diaper it really scares me as a mother to know I was giving my child these harmful tablets I hope that my son has no damage from them.

Individual Case Safety Report

10486072-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:White
Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds: Flintstones vitamins

Individual Case Safety Report

10486072-01-00-03

CaseID: 10501178

10501178-01-00-01

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Y reporting of
uct problems and
product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 5606832

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	14 Months (b) (6)	☑ Female ☐ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/03/2014	10/04/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Teething tablets
Strength: Hylands teething tablets
Manufacturer: Hylands

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/03/2014 - 10/03/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething baby
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
5497331271

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

CTU OCT - 6 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: (b) (6)
Address:
City: State: -- ZIP:

DSS OCT 06 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

Last night I used Hylands teething tablets, 2 of them on my 14 month old baby. That was the beginning of our nightmare! Within 20 minutes of giving this to our baby, she became anxious, jumpy, delerium set in and she was completely spaced out. My husband and I heard a pounding noise from her room around 1am, went in to check her and she was sitting in her crib spaced out banging her head on the crib railing. Then it seemed like she was hallucinating. She was babbling the few words she knows over and over and over for hours. Yet she was still spaced out, not acting herself. This was a very scary event for us as parents to Wittness. I know this was caused from the hylands teething tablets. Please look into this over the counter medicine.

Individual Case Safety Report

10501178-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:White
Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds: Infant Tylenol

Individual Case Safety Report

10501178-01-00-03

CaseID: 10510040

10510040-01-00-01

CDER

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Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

...Y reporting of
...uct problems and
product use errors

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 567351

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	1 Years (b) (6)	☐ Female ☑ Male	35 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/01/2014	10/08/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

CTU
OCT 09 2014

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hyland's Teething Tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount / Frequency / Route

	Dose or Amount	Frequency	Route
#1		--	--
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 04/25/2013 - 06/01/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
OCT 09 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

We believe the Hyland's teething tablet are causing my child to have seizures within 24 hours of giving them. Beginning of June, I decided to throw them all away and we have seizure free since. I have spent nights in the hospital for seizures, a few EEGs and MRIs have been done. We have had more than 10 seizures that have started back in 4/2013. He had the most seizures in 7/2013 when he was first two teeth were coming in. And I know I was giving him teething tablets then but just keep thinking it was ear infection related... But now I have a theory it was those tablets! And that make me mad/sad and disappointed.

Individual Case Safety Report

10510040-01-00-02

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

EEG: normal MRI: stated he has a hippocampal malformation

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:White
Medical Conditions: He was diagnosed with Febrile Seizures but not sure anymore
---
Allergies: n/a

Important Information: n/a

RX Meds:

OTC Meds: Children's Chewable Vitamin

Individual Case Safety Report

10510040-01-00-04

Individual Case Safety Report

10519215-01-00-01

CDER OTC

CaseID: 10519215

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Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY	
Triage unit sequence #	567825

13

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	9 Months (b) (6)	☑ Female ☐ Male	____ lb or 9.3 kg

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/10/2014 - 10/10/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Baby teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/12/2014	10/12/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hyland Teething Tablets
Strength:
Manufacturer: Hyland
#2 Name:
Strength:
Manufacturer:

E. SUSPECT MEDICAL DEVICE

1. Brand Name
CTU
2. Common Device Name
OCT 14 2014
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
See page 5 for complete text.

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)
SS
14 2014

Phone #	E-mail
(b) (6)	

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Pharmacists	☐ Manufacturer ☑ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

Pt was given Hyland Teething Tablets Friday evening. She was acting differently afterward. Pt was admitted (b) (6) for fever, dehydration, N/V, diarrhea, and recent head injury. Pt experienced a seizure (b) (6) during hospital stay

Individual Case Safety Report

10519215-01-00-02

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

Head CT on (b) (6) and (b) (6)

Individual Case Safety Report

10519215-01-00-03

CaseID: 10529024

Individual Case Safety Report

10529024-01-00-01

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Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	9 Months	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
07/00/2014 -- 09/00/2014	10/01/2014

5. Describe Event or Problem

MOTHER SAW THE FACEBOOK POST ABOUT SEIZURES AND BRAIN BLEEDS AND IS CONCERNED THAT WHENEVER SHE GIVES HER CHILD THE TEETHING TABLETS, HE STARTS SHAKING AND WAVING HIS ARMS LIKE HE'S EXCITED AND SQUEEZING HIS HANDS TOGETHER. SHE DOES NOT KNOW WHAT THIS IS BUT DOES NOT THINK IT'S A SEIZURE BECAUSE SHE HAD SEIZURES AS A CHILD. 9 MOS. OLD MALE. TAKING BABY TEETHING TABLETS 2 -3 SL BID X 2 MONTHS.

FOLLOW-UP 09/30/14: SHE CALLED THE DOCTOR AND HE SAID HE WILL LOOK INTO THIS WEEK AND SEND CHILD TO A NEUROLOGIST. CHILD IS INTERACTING WITH MOTHER DURING SHAKING BUT EACH TIME IT'S DIFFERENT. SOMETIMES CHILD SHAKES HIS HANDS AND LEGS, SOMETIMES JUST HIS HEAD, SOMETIMES JUST HIS ARMS. AFTER SHAKING HE'S BACK TO NORMAL. SHAKING GOES ON FOR UP TO 30 SECONDS BUT NOT LONGER. HIS FACE HAS AN EVIL SMILE WHEN HE'S SHAKING (LIKE A STRAIGHT SMILE WITH NO EMOTION). HAS NOT DONE SHAKEN SINCE SHE DISPOSED OF THE TABLETS. LAST EPISODE WAS ON SUNDAY, 09/28/2014.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

NONE

RECEIVED
OCT 16 2014
CDR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 2-3 TABS SL BID X 2 MOS	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 A46514	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: OCT 17 2014 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

OCT 16 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☑ No ☐ Unk.

Individual Case Safety Report

CaseID: 10529024

10529024-01-00-02

FDA USE ONLY

1. Check One
☐ User Facility ☐ Importer

2. Dr/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
EDYTA FRACKIEWICZ
Address
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address
STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
09/28/2014

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973 AE # 1562

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
OCT 17 2014

OCT 16 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report

10529024-01-00-03

MPLAINT RECORD

Ca[illegible]29024

COMPLAINT #: 2572

DATE OF COMPLAINT: 09/28/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A46514

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: MOTHER SAW THE FACEBOOK POST ABOUT SEIZURES AND BRAIN BLEEDS AND IS CONCERNED THAT WHENEVER SHE GIVES HER CHILD THE TEETHING TABLETS, HE STARTS SHAKING AND WAVING HIM ARMS LIKE HE'S EXCITED AND SQUEEZING HIS HANDS TOGETHER. SHE DOES NOT KNOW WHAT THIS IS BUT DOES NOT THINK IT'S A SEIZURE BECAUSE SHE HAD SEIZURES AS A CHILD. 9 MONTH OLD MALE. TAKING BABY TEETHING TABLETS 2 – 3 TABLETS UNDER TONGUE TWICE A DAY FOR 2 MONTHS. FOLLOW-UP 09/30/14: SHE CALLED THE DOCTOR AND HE SAID HE WILL LOOK INTO THIS WEEK AND SEND CHILD TO A NEUROLOGIST. CHILD IS INTERACTING WITH THE MOTHER DURING SHAKING BUT EACH TIME IT'S DIFFERENT. SOMETIMES CHILD SHAKES HIS HANDS AND LEGS, SOMETIMES JUST HIS HEAD, SOMETIMES JUST HIS ARMS. AFTER SHAKING HE'S BACK TO NORMAL. SHAKING GOES ON FOR UP TO 30 SECONDS BUT NOT LONGER. HIS FACE HAS AN EVIL SMILE WHEN HE'S SHAKING (LIKE A STRAIGHT SMILE WITH NO EMOTION). HAS NOT DONE SHAKING SINCE SHE DISPOSED OF THE TABLETS. LAST EPISODE WAS ON SUNDAY, 09/28/2014.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 09/28/2014

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: OCT 17 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1562

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/28/2014

BY: EDYTA FRACKIEWICZ

SECTION V:

OCT 16 2014

REVIEWED BY MANAGEMENT BY: RWatt

DATE: 10-07-14

BY: Eric Baum
QA / QC DIRECTOR

DATE: 10-07-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

Individual Case Safety Report

10529024-01-00-04

INDARD
PATHIC
USA SINCE 1903

Adverse Event
0039-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A46514, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A46514associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A46514. The Baby Teething bulk lot # 123453 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0646-2014) has been received for Hyland's Baby Teething Tablets lot # A46514. The complaints were reviewed and they do not appear to be related. A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A46514.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

10/6/14
Date

DSS
OCT 17 2014

OCT 16 2014

CC-0752-2014
AE-0443-2014

STANDARD
Individual Case Safety Report

10529024-01-00-05

Case ID: 10529024

Hyland's®

ISE EVENT DATA FORM

AE #: 1562 COMPLAINT #: 2572

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

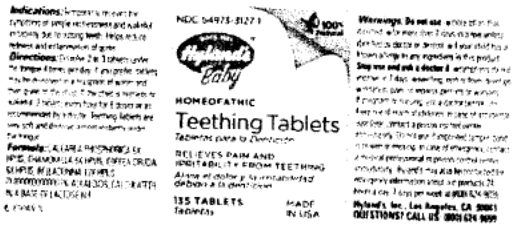
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

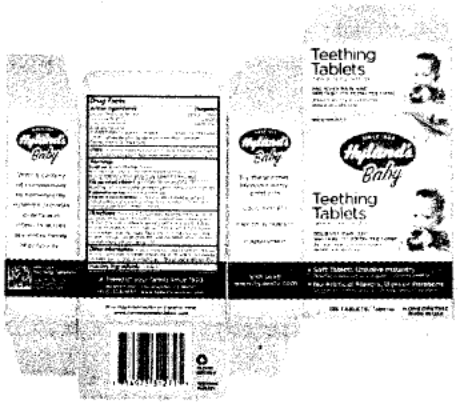
E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
OCT 17 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: TWelt DATE: 10-07-14

BY: Eric Bain DATE: 10-07-14
QA / QC DIRECTOR

OCT 16 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 10529055

Individual Case Safety Report

10529055-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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1 of 6

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	6 Months	☑ Female ☐ Male	____ lbs or ____ kgs
In confidence	Date of Birth: (b) (6)		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
09/00/2012 -- PRESENT	10/01/2014

5. Describe Event or Problem

THE REPORTER'S DAUGHTER, BEGAN TAKING "BABY TEETHING TABLETS" WHEN SHE WAS ABOUT 4 MONTHS OLD. THE REPORTER STATED THAT SHE GAVE THE TABLETS AS DIRECTED ON THE BOTTLE, 1 TABLET BY MOUTH EVERY 30 MINUTES, AND THAT SHE WAS VERY CAREFUL ABOUT THE DOSING BECAUSE SHE WAS VERY WARY ABOUT GIVING HER DAUGHTER ANY KIND OF MEDICATION OR SUPPLEMENT. PER THE REPORTER, THE "BABY TEETHING TABLETS" WERE ONLY GIVEN WHEN SYMPTOMS WERE PRESENT. THE REPORTER STATED THAT SHE HAD ALSO BEEN GIVING HER DAUGHTER "ORAJEL" FOR HER TEETHING. THE REPORTER STATED THAT HER DAUGHTER HAD HER FIRST SEIZURE WHEN SHE WAS 6 MONTHS OLD. PER THE REPORTER, SINCE THEN SHE HAD HAD 5 MORE SEIZURES AND WAS DIAGNOSED WITH EPILEPSY ABOUT 2 WEEKS AGO. THE REPORTER STATED THAT HER DAUGHTER HAD ABNORMAL BRAIN WAVES ON A "BRAIN SCAN". PER THE REPORTER, THE DOCTOR STATED THAT THESE SEIZURES ARE NOT CONSIDERED TO BE "GRAND MAL" BECAUSE THEY LAST FOR 3 MINUTES; PER THE REPORTER, THE DOCTOR STATED THAT "GRAND MAL" SEIZURES LAST FOR 5 OR MORE MINUTES. THE REPORTER STATED THAT HER DAUGHTER WAS NOW TAKING MEDICATION FOR THE SEIZURES. SHE STATED THAT SHE DISCONTINUED USING THE BABY TEETHING TABLETS" WHEN HER DAUGHTER STOPPED TEETHING, AT AROUND THE AGE OF 12 MONTHS. PER THE

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

BRAIN SCAN -- HAD ABNORMAL BRAIN WAVES

DIAGNOSED WITH EPILEPSY IN SEPTEMBER 2014 (ABOUT 2 WEEKS AGO).

CHILD'S SEIZURES WERE NOT CONSIDERED TO BE "GRAND MAL".

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 1TAB Q30MINS SX PRSNT	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1 OCT 16 2014	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)* | 7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

OCT 17 2014

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

OCT 16 2014

Phone # (b) (6) | Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☑ No ☐ Unk.

Individual Case Safety Report

CaseID: 10529055

10529055-01-00-02

FDA USE ONLY

1. [ ] User Facility [ ] Importer

2. Dr/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
[ ] Initial
[ ] Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
[ ] Yes ____ *(mm/dd/yyyy)*
[ ] No

12. Location Where Event Occurred
[ ] Hospital
[ ] Home
[ ] Nursing Home
[ ] Outpatient Treatment Facility
[ ] Outpatient Diagnostic Facility
[ ] Ambulatory Surgical Facility
[ ] Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
[ ] Yes ____ *(mm/dd/yyyy)*
[ ] No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
EDYTA FRACKIEWICZ
Address
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address
STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
[ ] Foreign
[ ] Study
[ ] Literature
[x] Consumer
[ ] Health Professional
[ ] User Facility
[ ] Company Representative
[ ] Distributor
[ ] Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
09/29/2014

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC Product [x] Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
[ ] 5-day [ ] 30-day
[ ] 7-day [ ] Periodic
[ ] 10-day [x] Initial
[x] 15-day [ ] Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973 AE # 1564

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
[ ] Death
[ ] Serious Injury
[ ] Malfunction

2. If Follow-up, What Type?
[ ] Correction
[ ] Additional Information
[ ] Response to FDA Request
[ ] Device Evaluation

3. Device Evaluated by Manufacturer?
[ ] Not Returned to Manufacturer
[ ] Yes [ ] Evaluation Summary Attached
[ ] No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
[ ] Yes [ ] No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
[ ] Recall
[ ] Repair
[ ] Replace
[ ] Relabeling
[ ] Notification
[ ] Inspection
[ ] Patient Monitoring
[ ] Modification/Adjustment
[ ] Other: ____

8. Usage of Device
[ ] Initial Use of Device
[ ] Reuse
[ ] Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. [ ] Additional Manufacturer Narrative and / or 11. [ ] Corrected Data

DSS
OCT 17 2014

OCT 16 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report

10529055-01-00-03

'INUATION PAGE)
by user-facilities,
utors, and manufacturers
)ATORY reporting

B.5. **Describe Event or Problem** *(continued)*

REPORTER, HER DAUGHTER WAS NOT HAVING SEIZURES IMMEDIATELY FOLLOWING ANY OF HER DOSES OF "BABY TEETHING TABLETS". PER THE REPORTER, NOBODY CORRELATED THE SEIZURES WITH THE "BABY TEETHING TABLETS"; SHE CALLED OUR EMERGENCY LINE NOW BECAUSE SHE SAW A POST ON FACEBOOK WHICH STATED THAT THE TEETHING TABLETS CAUSED SEIZURES.

Back to Item B.5

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

Back to Item B.6

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Back to Item B.7

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Back to Item C.10

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Other Remarks

Back to Item D.11

Individual Case Safety Report

10529055-01-00-04

COMPLAINT RECORD

Case 10529055

COMPLAINT #: 2574

DATE OF COMPLAINT: 09/29/14

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: THE REPORTER'S DAUGHTER, BEGAN TAKING "BABY TEETHING TABLETS" WHEN SHE WAS ABOUT 4 MONTHS OLD. THE REPORTER STATED THAT SHE GAVE THE TABLETS AS DIRECTED ON THE BOTTLE, 1 TABLET BY MOUTH EVERY 30 MINUTES, AND THAT SHE WAS VERY CAREFUL ABOUT THE DOSING BECAUSE SHE WAS VERY WARY ABOUT GIVING HER DAUGHTER ANY KIND OF MEDICATION OR SUPPLEMENT. PER THE REPORTER, THE "BABY TEETHING TABLETS" WERE ONLY GIVEN WHEN SYMPTOMS WERE PRESENT. THE REPORTER STATED THAT SHE HAD ALSO BEEN GIVING HER DAUGHTER "ORAJEL" FOR HER TEETHING. THE REPORTER STATED THAT HER DAUGHTER HAD HER FIRST SEIZURE WHEN SHE WAS 6 MONTHS OLD. PER THE REPORTER, SINCE THEN SHE HAS HAD 5 MORE SEIZURES AND WAS DIAGNOSED WITH EPILEPSY ABOUT 2 WEEKS AGO. THE REPORTER STATED THAT SHE HAD ABNORMAL BRAIN WAVES ON A "BRAIN SCAN". PER THE REPORTER, THE DOCTOR STATED THAT THESE SEIZURES ARE NOT CONSIDERED TO BE "GRAND MAL" BECAUSE THEY LAST FOR 3 MINUTES; PER THE REPORTER, THE DOCTOR STATED THAT "GRAND MAL" SEIZURES LAST FOR 5 OR MORE MINUTES. THE REPORTER STATED THAT HER DAUGHTER WAS NOW TAKING MEDICATION FOR THE SEIZURES. SHE STATED THAT SHE DISCONTINUED USING THE "BABY TEETHING TABLETS" WHEN HER DAUGHTER STOPPED TEETHING, AT AROUND THE AGE OF 12 MONTHS. PER THE REPORTER, HER DAUGHTER WAS NOT HAVING SEIZURES IMMEDIATELY FOLLOWING ANY OF HER DOSES OF "BABY TEETHING TABLETS". PER THE REPORTER, NOBODY CORRELATED THE SEIZURES WITH THE "BABY TEETHING TABLETS"; SHE CALLED OUR EMERGENCY LINE NOW BECAUSE SHE SAW A POST ON FACEBOOK WHICH STATED THAT THE TEETHING TABLETS CAUSED SEIZURES. THE REPORTER STATED THAT SHE WAS AT WORK AND ASKED IF SHE COULD CALL ME BACK; WHEN I STATED THAT I WOULD RETURN HER CALL IF I DIDN'T HEAR FROM HER, THE REPORTER SAID, "OH, THAT WOULD BE EVEN BETTER!" SHE STATED THAT SHE GETS OFF OF WORK AT 3:30 PM EST.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/29/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: CORRECTIVE ACTION:

DSS

OCT 17 2014

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1564

ADVERSE EVENT SERIOUS: (Y) / N

OCT 16 2014

ADVERSE EVENT REPORTED ON: 09/29/14

BY: (b) (6)

SECTION V:

REVIEWED BY MANAGEMENT BY: RWatt

DATE: 10-01-14

BY: Eric Bam
QA / QC DIRECTOR

DATE: 10-07-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

Individual Case Safety Report

10529055-01-00-05

TANDARD
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I THE USA SINCE 1903

)us Adverse Event
SAE-0041-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/6/14
Date

DSS
OCT 17 2014

OCT 16 2014

CC-0756-2014
AE-0445-2014

Case ID: 10529055

STANDARD

Individual Case Safety Report

10529055-01-00-06

Hyland's

:RSE EVENT DATA FORM

AE #: 1564

COMPLAINT #: 2574

SECTION I: **PATIENT INFORMATION** *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

DSS

OCT 17 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

OCT 16 2014

REVIEWED BY MANAGEMENT BY: DATE: 10-07-14

BY: QA / QC DIRECTOR DATE: 10-07-14

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 10530766

10530766-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

se by user-facilities,
tributors and manufacturers
NDATORY reporting

OTC

Mfr Report #	54973
UF/Importer Report #	

FDA Use Only

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	7 Months	☐ Female	lbs
In confidence	or	☑ Male	or
	Date of Birth:		kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☑ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
08/23/2012	10/01/2014

5. Describe Event or Problem

CHILD HAD AN ACCIDENT ON (b) (6) BABY WAS 7 MONTHS OLD HOLDING ON TO AN OTTOMAN AND HE LANDED ON HIS HEAD ON A CONCRETE / MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY -- PART OF HIS SKULL WAS REMOVED TO RELIEVE BRAIN SWELLING. 5 DAYS LATER THE DOCTORS FOUND ANOTHER OLDER BRAIN BLEED. HE WAS DIAGNOSED WITH SHAKEN BABY SYNDROME BUT HAD NO BROKEN BONES OR OTHER SIGNS OF INJURY. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WEAK ON THE RIGHT SIDE, AND RETINAL HEMORRHAGING WHICH MADE HIM BLIND IN ONE EYE (NONE OF THIS PRESENT BEFORE HE FELL -- DUE TO HEAD INJURY). DOCTORS ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMORRHAGE UPON EVALUATION OF THE HEAD INJURY. MOTHER WANTS TO KNOW IF OLD RETINAL BLEED THEY FOUND WAS DUE TO BABY TEETHING TABLETS BECAUSE DOCTORS THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS WHEN THE CHILD WAS 5 MONTHS OLD.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

HOSPITALIZED AND HAD SURGERY FOR A BRAIN BLEED. 5 DAYS LATER DOCTORS FOUND ANOTHER OLDER BRAIN BLEED. DIAGNOSED WITH SHAKEN BABY SYNDROME.

RECEIVED
OCT 17 2014
CDR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

ON (b) (6) 7 MONTH OLD CHILD WAS HOLDING ON TO AN OTTOMAN AND HE LANDED ON HIS HEAD ON A CONCRETE / MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES.
CHILD HAS CEREBRAL PALSY, IS WEAK ON THE RIGHT SIDE, AND RETINAL HEMORRHAGING. DOCTORS ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMORRHAGE UPON EVALUATION OF THE HEAD INJURY.
CHILD BORN PREMATURE DUE TO MOTHER'S PREECLAMPSIA.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 1/2TABSLQ6-8HRS;1TABSL	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
OCT 20 2014

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

OCT 17 2014

Phone #	Email Address
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

PLEASE TYPE OR USE BLACK INK

10530766-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual) Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source (Check all that apply) ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer (mm/dd/yyyy): 09/29/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report (Check all that apply) ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): BRAIN AND RETINAL HEMORRHAGE, SEIZURE, HEAD INJURY, CEREBRAL PALSY, RIGHT SIDED WEAKNESS, BLIND
9. Manufacturer Report Number: 54973 AE # 1563

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____
4. Device Manufacture Date (mm/yyyy)
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes (Refer to coding manual) Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___ Method ___ - ___ - ___ - ___ Results ___ - ___ - ___ - ___ Conclusions ___ - ___ - ___ - ___
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
OCT 20 2014 OCT 17 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
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OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report

10530766-01-00-03

R COMPLAINT RECORD

CaseID: 10530766

COMPLAINT #: 2573

DATE OF COMPLAINT: 09/29/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: NOT AVAILABLE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CHILD HAD AN ACCIDENT ON (b) (6) BABY WAS 7 MONTHS OLD HOLDING ON TO AN OTTOMAN AND HE LANDED ON HIS HEAD ON A CONCRETE / MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY – PART OF HIS SKULL WAS REMOVED TO RELIEVE BRAIN SWELLING. 5 DAYS LATER THE DOCTOR'S FOUND ANOTHER OLDER BRAIN BLEED. HE WAS DIAGNOSED WITH SHAKEN BABY SYNDROME BUT HAD NO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICES TOOK THE BABY AWAY AND PARENTS HAVE NOT HAD CUSTODY FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PARENTS. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WEAK ON THE RIGHT SIDE, AND RETINAL HEMORRHAGING WHICH MADE HIM BLIND IN ONE EYE (NONE OF THIS PRESENT BEFORE HE FELL – DUE TO HEAD INJURY). DOCTOR'S ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMORRHAGE WHICH WERE FOUND WHEN HE WENT TO THE HOSPITAL FOR THE HEAD INJURY. MOTHER WANTS TO KNOW IF OLD RETINAL BLEED THEY FOUND WAS DUE TO BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS WHEN THE CHILD WAS 5 MONTHS. GAVE ½ TABLET IN HIS MOUTH EVERY 6 – 8 HOURS AS NEEDED X 2 MONTHS UNTIL CHILD WENT TO THE HOSPITAL (AT 6 MONTHS INCREASED DOSE BY GIVING HIM A FULL TABLET). MOTHER IS TRYING TO GET HER BABY BACK AND LAYING OUT ALL ACTIONS. HER FIRST COURT HEARING IS NOVEMBER 3RD. CUSTOMER SENT THE FOLLOWING E-MAIL ON 09/24/14: HELLO, I WAS WONDERING IF YOU HAD ANY COMPLICATIONS IN 2012. I STARTED GIVING THEM TO MY SON JUNE/JULY OF 2012 AND I'M (b) (6) HE HAD AN ACCIDENT AND HAD A BRAIN BLEED. I CAN NOT EXPLAIN THE BLEED AND THEY TOOK MY SON OFF OF ME. WE BOUGHT THE TABLETS FROM WALMART IN (b) (6) (b) (6) THANK YOU FOR ANY HELP!

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/29/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS

OCT 20 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1563

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/29/14

BY: EDYTA FRACKIEWICZ

SECTION V:

OCT 17 2014

REVIEWED BY MANAGEMENT BY:

DATE: 10-07-14

BY:

QA / QC DIRECTOR

DATE: 10-07-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10530766-01-00-04

STANDARD HOMEOPATHIC
SINCE USA SINCE 1903

Serious Adverse Event
SAE-0040-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/6/14
Date

DSS
OCT 20 2014

OCT 17 2014

CaseID: 10530766

10530766-01-00-05

RSE EVENT DATA FORM

AE #: 1563 COMPLAINT #: 2573

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

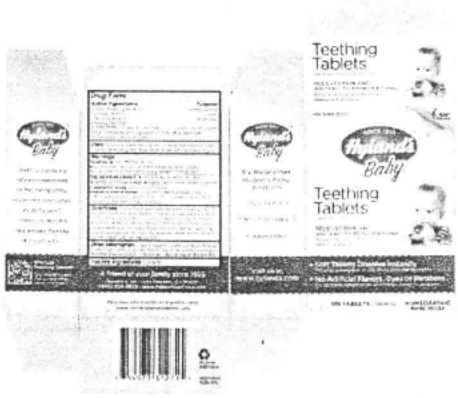
PHONE #: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE: DSS OCT 20 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DWalt DATE: 10-07-14 OCT 17 2014

BY: Eric Bain DATE: 10-07-14
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

10530771-01-00-01

CaseID: 10530771

OTC

...by user-facilities, ...ibutors and manufacturers ...DATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

MFR Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	9 Months	☐ Female	____ lbs
In confidence	or ____ Date of Birth:	☑ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
02/00/2013 & 04/00/2013	10/01/2014

5. Describe Event or Problem

BABY STARTED USING TEETHING TABLETS AT 3 MONTHS OLD IN AUGUST 2012. CHILD HAD GERD (GAS) AT ONE MONTH OLD, MOTHER SWITCHED FORMULAS AND HE WAS BETTER. NO MEDICATION WAS PRESCRIBED. CURRENT HEALTH: HE IS PRONE TO GET FEVERS SINCE THE SEIZURES, ONCE A MONTH, OR TWO. THE PARENTS CAREFULLY MONITOR HIS FEVERS AND GIVE TYLENOL AND IBUPROFEN ALTERNATELY WHEN FEVER OCCURS. MOTHER CONTINUED TO GIVE TEETHING TABLETS UNTIL HIS LAST TEETH EMERGED IN JANUARY 2014. SHE SAID HE "GOT HIS TEETH QUICKLY". AT THE HOSPITAL THEY DID NEUROLOGICAL WORKUP, EEG, EPILEPTIC STRESS TEST, AND DIAGNOSED IT AS "COMPLEX FEBRILE SEIZURES". MOTHER SAID DOCTOR WAS CURIOUS THAT THERE WAS NO FAMILY HISTORY OF IT. BABY WAS PRESCRIBED DIAZEPAM IF HE HAS ANOTHER SEIZURE. HAS HAD NONE SINCE. DOCTORS SAID TEETHING DID NOT CAUSE FEVER BUT HE ALWAYS HAD FEVER DURING HIS TEETHING PHASES. MOTHER CALLED AFTER READING AN ONLINE POST ABOUT TEETHING TABLETS AND WONDERED IF THAT COULD EXPLAIN THE CAUSE OF HER SON'S SEIZURES.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

NEUROLOGICAL WORKUP, EEG, EPILEPTIC STRESS TEST CONDUCTED. DIAGNOSED AS "COMPLEX FEBRILE SEIZURES".

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO FAMILY HISTORY OF SEIZURES.

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CDR

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

TYLENOL AND IBUPROFEN GIVEN ALTERNATELY WHEN FEVER OCCURS.

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Unique Identifier (UDI) #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

DSS
OCT 20 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

OCT 17 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 10530771

10530771-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ___ - ___ - ___; Device Code ___ - ___ - ___
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address:

HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 09/29/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURES

9. Manufacturer Report Number: 54973 AE # 1561

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ___ - ___ - ___; Device Code ___ - ___ - ___; Method ___ - ___ - ___ - ___; Results ___ - ___ - ___ - ___; Conclusions ___ - ___ - ___ - ___
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
OCT 20 2014

OCT 17 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report

10530771-01-00-03

COMPLAINT RECORD

CaseID: 10530771

COMPLAINT #: 2571

DATE OF COMPLAINT: 09/29/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABLETS

LOT NO.: THREW BOTTLES OUT

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SON HAD 3 SEIZURES LAST YEAR IN 2013 "COMPLEX FEBRILE SEIZURES" WITH NO FAMILTY HISTORY. HAD HAD FEVER OF 103.7°F AFTER SEIZURE AND 99.2°F PRIOR TO THE FIRST SEIZURE. HE WAS TAKING ACETAMINOPHEN AND TEETHING TABLETS AT THE TIME. FIRST SEIZURE WAS IN FEBRUARY 2013. (HE WAS BORN IN (b) (6)). SECOND SEIZURE WAS IN (b) (6) WHILE IN THE HOSPITAL THAT SAME DAY, HE HAD A THIRD SEIZURE. BABY STARTED USING TEETHING TABLETS AT 3 MONTHS OLD IN AUGUST 2012. CHILD HAD GERD (GAS) AT ONE MONTH OLD, MOTHER SWITCHED FORMULAS AND HE WAS BETTER. NO MEDICATION WAS PRESCRIBED. CURRENT HEALTH: HE IS PRONE TO GET FEVERS SINCE THE SEIZURES, ONCE A MONTH, OR TWO. THE PARENTS CAREFULLY MONITOR HIS FEVERS AND GIVE TYLENOL AND IBUPROFEN ALTERNATELY WHEN FEVER OCCURS. MOTHER CONTINUED TO GIVE TEETHING TABLETS UNTIL HIS LAST TEETH EMERGED IN JANUARY 2014. SHE SAID HE "GOT HIS TEETH QUICKLY". AT THE HOSPITAL THEY DID NEUROLOGICAL WORKUP, EEG, EPILEPTIC STRESS TEST, AND DIAGNOSED IT AS "COMPLEX FEBRILE SEIZURES". MOTHER SAID DOCTOR WAS CURIOUS THAT THERE WAS NO FAMILY HISTORY OF IT. BABY WAS PRESCRIBED DIAZEPAM IF HE HAS ANOTHER SEIZURE. HAS HAD NONE SINCE. DOCTORS SAID TEETHING DID NOT CAUSE FEVER BUT HE ALWAYS HAD FEVER DURING HIS TEETHING PHASES. MOTHER CALLED AFTER READING AN ONLINE POST ABOUT TEETHING TABLETS AND WONDERED IF THAT COULD EXPLAIN THE CAUSE OF HER SON'S SEIZURES.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 09/29/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: TUTTI GOLD

SECTION III: **CORRECTIVE ACTION:**

DSS

OCT 20 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1561

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/29/14 BY: TUTTI GOULD

SECTION V:

OCT 17 2014

REVIEWED BY MANAGEMENT BY: DATE: 10-07-14

BY: QA / QC DIRECTOR DATE: 10-07-14

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

10530771-01-00-04

INDARD
OPATHIC
E USA SINCE 1903

Serious Adverse Event
SAE-0038-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/6/14
Date

DSS
OCT 20 2014

OCT 17 2014

10530771-01-00-05

RSE EVENT DATA FORM

AE #: 1561 COMPLAINT #: 2571

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

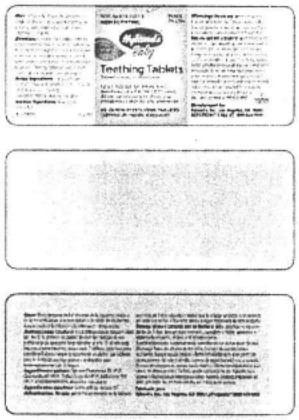
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

DSS

OCT 20 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-07-14

BY: QA / QC DIRECTOR DATE: 10-07-14

OCT 17 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 10530789

10530789-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

se by user-facilities, tributors and manufacturers NDATORY reporting

OTC

Mfr Report # 54973

IUF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence

2. Age at Time of Event: 35 Months or ____ Date of Birth:

3. Sex: ☐ Female ☑ Male

4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy)
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 00/00/2005 -- 00/00/2006

4. Date of This Report (mm/dd/yyyy): 10/01/2014

5. Describe Event or Problem

FROM THE AGE OF 6 MONTHS TO 1 YEAR OLD CHILD WAS USING HYLAND'S TEETHING TABLETS. CHILD IS CURRENTLY 11 YEARS OLD. AT 2 YEARS 11 MONTHS OLD DEVELOPED SEIZURES AND EPILEPSY. HE HAD FOUR DIFFERENT KINDS: GRAND MAL WITH LIMP, SHAKING BODY; ABSENCE SEIZURES; DROP ATTACH SEIZURES; STARING SPELLS. RESOLVED WHEN HE WAS 4 YEARS OLD.

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(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN TESTS

DEVELOPED SEIZURES AND EPILEPSY AT 2 YEARS 11 MONTHS OLD.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

DOCTORS SAID THAT HE WOULD HAVE SEIZURES THE REST OF HIS LIFE BUT HE HAS NO SEIZURES NOW.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 UNKNOWN DOSE X 6 MOS
#2

3. Therapy Dates (If unknown, give duration from/to (or best estimate))
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Unique Identifier (UDI) #

5. Operator of Device
☐ Health Professional
☐ Lay User/Patient
☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

(b) (6) USA

DSS
OCT 20 2014

OCT 17 2014

Phone # (b) (6)

Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☑ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

FDA USE ONLY

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ___ - ___ - ___; Device Code ___ - ___ - ___
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other: ____

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 09/30/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURES, EPILEPSY

9. Manufacturer Report Number: 54973 AE # 1566

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ___ - ___ - ___; Device Code ___ - ___ - ___; Method ___ - ___ - ___ - ___; Results ___ - ___ - ___ - ___; Conclusions ___ - ___ - ___ - ___
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

OCT 17 2014

OCT 20 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

10530789-01-00-03

R COMPLAINT RECORD

COMPLAINT #: 2576

DATE OF COMPLAINT: 09/30/14

PRODUCT: HYLAND'S TEETHING TABLETS

ITEM CODE: TEET----T125

SIZE: 125 TABLETS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SAW THE FACEBOOK POST ABOUT SEIZURES. FROM THE AGE OF 6 MONTHS TO 1 YEAR OLD CHILD WAS USING HYLAND'S TEETHING TABLETS. CHILD IS CURRENTLY 11 YEARS OLD. AT 2 YEARS 11 MONTHS OLD DEVELOPED SEIZURES AND EPILEPSY. DOCTOR'S SAID THAT HE WOULD HAVE SEIZURES THE REST OF HIS LIFE BUT HE HAS NO SEIZURES NOW. HE HAD FOUR DIFFERENT KINDS: GRAND MAL WITH LIMP, SHAKING BODY; ABSENCE SEIZURES; DROP ATTACH SEIZURES; STARING SPELLS. RESOLVED WHEN HE WAS 4 YEARS OLD WHEN ANOTHER BABY IN THE FAMILY WAS BORN. DOCTORS CAN'T EXPLAIN HOW SEIZURES RESOLVED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/30/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: OCT 20 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1566

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/30/14 BY: EDYTA FRACKIEWICZ

OCT 17 2014

SECTION V:

REVIEWED BY MANAGEMENT BY: [signature] DATE: 10-07-14

BY: [signature] DATE: 10-07-14
QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10530789-01-00-04

STANDARD OPATHIC
HOMEOPATHIC USA SINCE 1903

Serious Adverse Event
SAE-0038-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/6/14
Date

DSS
OCT 20 2014

DSS
OCT 20 2014

OCT 17 2014

CC-0758-2014
AE-0447-2014

10530789-01-00-05

Hyland's

?SE EVENT DATA FORM

AE #: 1566 COMPLAINT #: 2576

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

DSS
OCT 20 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-07-14

BY: QA / QC DIRECTOR DATE: 10-07-14

OCT 17 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

10542710-01-00-01

CaseID: 10542710

TC

...se by user facilities, ...ributors and manufacturers ...NDATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	14 Months or Date of Birth:	☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/00/2013 -- PRESENT	10/06/2014

5. Describe Event or Problem

CHILD DEVELOPED SEIZURES AROUND THE AGE OF 3 MONTHS WHEN MOTHER STARTED GIVING HIM THE BABY TEETHING TABLETS. CHILD SHAKES REALLY BADLY, ESPECIALLY WHEN HE IS SLEEPING, WHEN HE HAS THE SEIZURE. HE IS GOING TO HAVE AN EEG ON OCTOBER 16TH. CHILD HAD A FEVER OF 99.8F WITH THE LAST SHAKING. BEFORE THAT HE HAS HAD FEVERS OF 101F AND 102F AND WOULD ALSO SHAKE. HE HAS A HISTORY OF HAVING HIGH FEVERS. DOCTOR DOES NOT ATTRIBUTE THE SEIZURES TO THE FEVERS.

Received

OCT 23 2014

CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

HISTORY OF HIGH FEVERS.

NO FAMILY HISTORY OF SEIZURES.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 UNKNOWN DOSE IN WATER	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A519C	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Unique Identifier (UDI) #	☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

OCT 24 2014

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone #	Email Address
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

OCT 28 2014

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 10542710

10542710-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person
5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address:
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 09/29/2014

5. (A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES, FEVERS

9. Manufacturer Report Number
54973 AE # 1569

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
OCT 24 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

OCT 23 2014

10542710-01-00-03

COMPLAINT RECORD

10542710

COMPLAINT #: 2579

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 09/29/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A519C (PER CUSTOMER)

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL ON SEPTEMBER 29: SINCE I HAVE BEEN GIVING THE TEETHING TABLETS TO MY SON HE KNOW HAS SEIZURES BECAUSE OF THE PRODUCT. I SEEN ALL OVER FACEBOOK THAT YOU GUYS HAD A RECALL OUT FOR IT. I SPOKE WITH CUSTOMER ON SEPTEMBER 30TH. SHE REPORTED THAT SHE STARTED GIVING HER CHILD BABY TEETHING TABLETS AT 3 MONTHS AND AROUND THAT TIME HE DEVELOPED SEIZURES. SHE WAS GIVING THEM IN WATER AND PUTTING THEM ON THE BABY'S GUMS. USING THEM EVERY OTHER DAY X 11 MONTHS. SHE IS UNSURE OF WHAT TYPE OF SEIZURES HER CHILD HAS BUT HE SHAKES REALLY BADLY, ESPECIALLY WHEN HE IS SLEEPING. HE IS GOING TO HAVE AN EEG ON OCTOBER 16TH. SHE PROVIDED A LOT # OF A519C WHICH SHE READ OFF THE BOTTOM OF THE BOTTLE. I TOLD HER THAT IT'S NOT A HYLAND'S LOT # AND TO LOOK AT THE SIDE OF THE LABEL, AND SHE SAID THAT SHE COULD NOT SEE A LOT # THERE. CALLED CUSTOMER AGAIN ON 10/01/14 FOR FOLLOW-UP INFORMATION: MOTHER STATED THAT THERE IS NO FAMILY HISTORY OF SEIZURES. BABY HAD A FEVER WITH THE LAST SHAKING 99.8°F. BEFORE THAT HE HAD FEVERS OF 101 AND 102°F AND WOULD ALSO SHAKE. HE HAS A HISTORY OF HAVING HIGH FEVERS. DOCTOR SAID TO HER THAT THESE FEVERS ARE NORMAL IN A CHILD AND DID NOT ATTRIBUTE THE SEIZURES TO THE FEVERS. DOCTOR SAID THAT FEVERS COULD HAVE BEEN CAUSED BY CHANGING ENVIRONMENTS BECAUSE MOTHER WAS LIVING FROM HOTEL TO HOTEL. SHE THREW THE BOTTLE AWAY. STOP USING BABY TEETHING TBALETS AND CONSULT YOUR PHYSICIAN REGARDING YOUR CHILD'S SYMPTOMS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/29/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS
OCT 24 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1569

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/29/14 BY: EDYTA FRACKIEWICZ

OCT 28 2014

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 10-10-14

BY:

QA / QC DIRECTOR

DATE: 10-10-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10542710-01-00-04

ANDARD
OPATHIC
HE USA SINCE 1903

Serious Adverse Event
SAE-0045-2014

Product in Inventory:

The lot number provided by the customer for the Hyland's Baby Teething Tablets (BTET) lot # A519C but after a search of our systems it was determined that it does not exist.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq^{(b)(4)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/8/14
Date

DSS
OCT 24 2014

CC-0771-2014
AE-0455-2014

OCT 28 2014

Individual Case Safety Report

10542710-01-00-05

CaseID: 10542710

Hyland's®

:RSE EVENT DATA FORM

AE #: 1569 COMPLAINT #: 2579

SECTION I: **PATIENT INFORMATION** *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

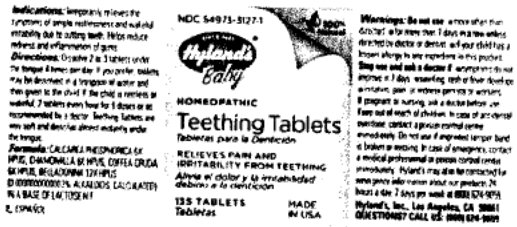
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

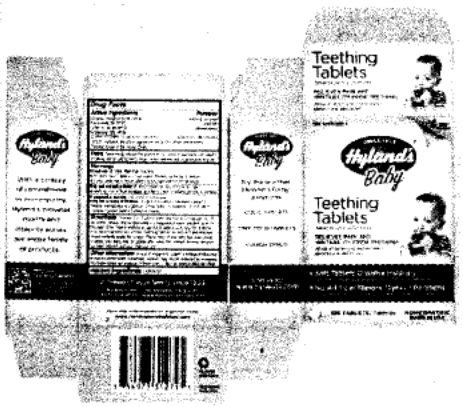
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
OCT 24 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-10-14

BY: QA / QC DIRECTOR DATE: 10-10-14

DISTRIBUTION: FDA ADVERSE EVENT FILE

OCT 28 2014 SAE01

10542735-01-00-01

CaseID: 10542735

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...e by user facilities,
...ributors and manufacturers
...DATORY reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

...EDWATCH

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	1 Years	☑ Female ☐ Male	lbs or kgs
In confidence	or Date of Birth:		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☑ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
01/00/2009 - PRESENT	10/08/2014

5. Describe Event or Problem

MOTHER POSTED ON (b) (6) THAT 6 YEAR OLD DAUGHTER HAS MOTOR FUNCTION DELAYS AFTER USE OF TEETHING TABLETS AS AN INFANT. DID NOT TALK UNTIL SHE WAS 3 YEARS OLD AND ONLY SPOKE 40 WORDS AT THE TIME.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO HISTORY OF DEVELOPMENTAL DELAYS IN PARENTS. OLDER BROTHER ALSO HAS SIMILAR SYMPTOMS SAME AS SIBLING.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
#1 AS DIRECTED ON LABEL	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Unique Identifier (UDI) #	☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

USA

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

10542735-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____; Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 10/04/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SPEECH AND MOTOR FUNCTION DELAYS
9. Manufacturer Report Number: 54973 AE # 1573

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____; Device Code ____ - ____ - ____; Method ____ - ____ - ____ - ____; Results ____ - ____ - ____ - ____; Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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OCT 28 2014

10542735-01-00-03

:OMPLAINT RECORD

10542735

7008148
0005 0169
7117

COMPLAINT #: 2583

TAKEN BY: EDYTA FRACKIEWICZ DATE OF COMPLAINT: 10/04/14

PRODUCT: HYLAND'S TEETHING TABLETS ITEM CODE: TEET

SIZE: UNKNOWN LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (b) (6) ON (b) (6) I JUST FOUND OUT THAT THESE TABLETS WERE VOLUNTARILY RECALLED BY THE HYLAND'S COMPANY IN 2010. THEN AFTER THEY PUT A CHILD RESISTANT LID ON THEIR PRODUCT PUT IT BACK ON THE SHELVES. THIS PRODUCT CONTAINS AN INGREDIENT CALLED BELLADONNA. NOW TO THOSE OF YOU WHO DO NOT KNOW WHAT BELLADONNA IS HERE IS A DESCRIPTION CEN.M.WIKIPEDIA.ORG/WIKI/ATROPA_BELLADONNA. IT IS THE MOST TOXIC PLANT IN THE NORTHERN HEMISPHERE. AND YET WE HAVE BEEN GIVING THIS TO OUR BABIES!!! I DON'T BELIEVE EVERYTHING I SEE ONLINE BUT THIS ONE I FOUND I NEEDED TO RESEARCH. MMY SON WAS BORN IN 2004 I WAS TOLD ABOUT THESE AMAZING TEETHING TABLETS FROM A FRIEND. I USED THEM FOR ALL 3 OF MY KIDS. NOW MY 2 OLDER CHILDREN NOW AGES 10 AND 6 BOTH HAVE THE SAME EXACT MOTOR FUNCTION DELAYS. BOTH SPEECH AND OT. BOTH HAVING TO DO WITH THE BRAIN. NOW I AM NOT SAYING THAT THESE TABLETS ARE DEFINITELY THE CAUSE OF THEIR DELAYS BUT IT SEEMS PRETTY ODD THAT THEY WERE BORN COMPLETELY HEALTHY AND NEVER HAD ANY PROBLEMS UNTIL AFTER THEIR FIRST BIRTHDAYS. MY OLDER DAUGHTER DID NOT TALK UNTIL SHE WAS 3 AND EVEN THEN SHE ONLY HAD AROUND 40 WORDS IF THAT. MY SON HAS BEEN STRUGGLING WITH SPEECH, OT, READING, ATTENTION SPAN, MEMORY AND A LOT MORE. THE THING THAT GETS ME IS THAT THEY HAVE THE SAME EXACT SYMPTOMS. WHAT ARE THE ODDS?? I USED THESE TABLETS AS DIRECTED FOR BOTH OF THEM EVERYDAY WHILE THEY WERE TEETHING. FOR MONTHS AT A TIME. THEY SEEMED TO WORK GREAT!!! I NEVER THOUGHT THAT THERE WOULD BE PROBLEMS LATER ON. THE BOTTLE SAYS HOMEOPATHIC. THAT'S GOOD RIGHT? WRONG. HOMEOPATHIC DOES NOT MEAN SAFE! I KNOW THAT NOW. MY SON IS 10 AND IS A SPECIAL EDUCATION CLASS. HE STRUGGLES CONSTANTLY WITH EVERYTHING. HE HAD THESE TABLETS ON A DAILY BASIS FROM THE AGE OF 9 *(CONTINUED ON NEXT PAGE)*

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: Please see attached Investigation Report.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/04/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1573

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/04/14 BY: EDYTA FRACKIEWICZ

DSS
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SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 10-14-14

BY: QA / QC DIRECTOR DATE: 10-14-14

cc: QA / QC Production
Packaging Shipping / Receiving

OCT 23 2014 Form # VD1

10542735-01-00-04

2582

COMPLAINT #2582:
(b) (6)

NATURE OF COMPLAINT (CONT):

MONTHS UNTIL HE WAS FINISHED TEETHING. HE WAS MY FIRST BABY. AND ANYONE WHO HAS MORE THAN ONE CHILD KNOWS HOW PARANOID YOU ARE WITH YOUR FIRST. I WAS SCARED TO USE THE TABLETS AT FIRST. BUT MY HUSBAND TRIED THEM WHEN I WAS NOT HOME AND THEY WORKED. THEY MADE A SCREAMING BABY CALM DOWN AND BE PAIN FREE. LEARNING ALL OF THE NEW NEWS I'M HEARING ABOUT THESE TABLETS IS REALLY SCARING ME. ESPECIALLY WITH THE WAY MY CHILDREN ARE. NO KNOWN CAUSE. DOESN'T RUN IN THE FAMILY. PARENTS NEVER HAD DELAYS OR ANY PROBLEMS GROWING UP. I WANT TO REACH OUT TO OTHER PARENTS WHO HAVE USED THESE TABLETS. I WANT TO KNOW ABOUT YOUR CHILDREN'S SYMPTOMS IF ANY. ANY INFORMATION WILL HELP ME MAKE A POSSIBLE CASE AGAINST THIS COMPANY AND TO WARN POISONOUS PLANT EXTRACTS IN THE WORLD. PLEASE RE-THINK GIVING YOUR BABIES THESE TABLETS. I WISH I KNEW ALL THIS INFORMATION YEARS AGO. IT WOULD HAVE SAVED ME COUNTLESS YEARS OF ANGUISH. PLEASE COMMENT IF YOU HAVE SEEN ANY SYMPTOMS IN YOUR BABY OR CHILDREN. I WILL BE MAKING A FB PAGE AND WILL POST THE LINK HERE IF YOU WOULD LIKE TO JOIN TO BE UPDATED OF ANY FINDINGS.

HYLAND'S POSTED ON FACEBOOK ON 10/06/14: HYLAND'S IS COMMITTED TO FOLLOWING UP ON REPORTS OF ADVERSE EVENTS AND WOULD ASK YOU TO PLEASE CONTACT OUR PRODUCT INFORMATION SERVICE AS SOON AS POSSIBLE AT 1-800-624-9659 EXT. 4117 TO DISCUSS WHAT HAPPENED WITH YOUR CHILD AND FOR MORE INFORMATION ABOUT THE PRODUCT. AS A GENERAL GUIDELINE, WE ENCOURAGE ALL CONSUMERS TO CONTACT COMPANIES BY PHONE AT THE NUMBER PROVIDED RATHER THAN POSTING ON (b) (6) WHEN THEY ARE CONCERNED ABOUT A REACTION TO A MEDICINE SO THAT ANY ISSUES CAN BE PROPERLY ADDRESSED. PLEASE KNOW THAT HYLAND'S BABY TEETHING TABLETS HAVE A VERY WIDE MARGIN OF SAFETY, AS DO ALL HOMEOPATHICALLY-PREPARED MEDICINES.

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OCT 23 2014

10542735-01-00-05

STANDARD HOMEOPATHIC
THE USA SINCE 1903

Serious Adverse Event
SAE-0050-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/10/14
Date

DSS
OCT 24 2014

CC-0803-2014
AE-0475-2014

OCT 23 2014

Individual Case Safety Report

CaseID: 10542735

10542735-01-00-06

Hyland's

RSE EVENT DATA FORM

AE #: 1573 COMPLAINT #: 2583

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
OCT 24 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWatt DATE: 10-14-14

BY: Eric Bain DATE: 10-14-14
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

OCT 28 2014

FORM SAE01

Individual Case Safety Report

CaseID: 10542775

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

10542775-01-00-01

se by user-facilities, tributors and manufacturers NDATORY reporting

OTC

Page 1 of ___

Mfr Report # 54973
UF/Importer Report #
FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	9 Months or Date of Birth:	☐ Female ☑ Male	22 lbs or ___ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: ___ (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
09/19/2014	10/07/2014

5. Describe Event or Problem

9 MONTH OLD BABY HAD A SEIZURE ON (b) (6) AFTER BEING ON TEETHING TABLETS FOR 4 - 5 WEEKS. IT CAME ON AFTER HIS BATH AS MOTHER WAS RUBBING LOTION ON HIS LEGS. SHE SAID IT WAS AS THOUGH HE WAS SHIVERING. HIS LEGS THEN RHYTHMICALLY TIGHTENED AND LOOSENED. THIS SHAKING SPREAD TO THE REST OF HIS BODY AND LASTED 20 MINUTES. 911 WAS CALLED AND THE POLICE AND AMBULANCE ARRIVED; BABY'S TONGUE WAS HELD DOWN BY A TONGUE DEPRESSOR AND WAS TRANSFERRED TO THE CHILDREN'S HOSPITAL WHERE HE WAS OBSERVED FOR 4 DAYS. MOTHER SAID THAT SHE HAD GIVEN THE BABY 3 TABLETS OF TEETHING PRODUCT THE DAY BEFORE THE SEIZURE.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

A 36-HOUR EEG TEST SHOWED [illegible] OF UNKNOWN ORIGIN. ALL OTHER TESTS WERE NORMAL (MRI, CAT SCAN AND BLOOD WORK). DOCTORS PRESCRIBED PHENOBARBITAL UNTIL OCTOBER 15TH WHEN ANOTHER [illegible] WAS DONE.

Received
OCT 23 2014

CDR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

THERE IS NO HISTORY OF EVER HAVING ANY COLDS, FEVERS OR RASHES. HIS LAST IMMUNIZATION WAS JUNE 10TH, 2014; HE HAS ALSO RECEIVED REGULAR FLU SHOTS.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 2-3 TABS ONCE A WEEK	#1
#2	#2

4. Diagnosis for Use (Indication)

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Exp. Date
#1 A05014	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-3

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient
Serial #	Unique Identifier (UDI) #	☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

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OCT 24 2014

10. Device Available for Evaluation? (Do not send to FDA)

☐ Yes ☐ No ☐ Returned to Manufacturer on: ___ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

OCT 23 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

Individual Case Safety Report

CaseID: 10542775

10542775-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 10/02/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURE
9. Manufacturer Report Number: 54973 AE # 1571

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report

10542775-01-00-03

COMPLAINT RECORD

10542775

COMPLAINT #: 2581

DATE OF COMPLAINT: 10/02/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS ITEM CODE: BTET

SIZE: UNKNOWN LOT NO.: A05014

REPORTER: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: 9 MONTH OLD BABY HAD A SEIZURE ON (b) (6) AFTER BEING ON TEETHING TABLETS FOR 4 – 5 WEEKS. IT CAME ON AFTER HIS BATH AS MOTHER WAS RUBBING LOTION ON HIS LEGS. SHE SAID IT WAS AS THOUGH HE WAS SHIVERING, HIS LEGS THEN RHYTHMICALLY TIGHTENED AND LOOSENED. THIS SPREAD TO THE REST OF HIS BODY AND LASTED 20 MINUTES. 911 WAS CALLED AND THE POLICE AND AMBULANCE ARRIVED; BABY'S TONGUE WAS HELD DOWN BY A TONGUE DEPRESSOR. BABY WAS TRANSFERRED TO THE CHILDREN'S HOSPITAL AND STAYED FOR 4 DAYS. A 36-HOUR EEG TEST SHOWED A "SMALL SPIKE" OF UNKNOWN ORIGIN. ALL OTHER TESTS WERE NORMAL (MRI, CAT SCAN AND BLOOD WORK). DOCTORS PRESCRIBED PHENOBARBITAL UNTIL OCTOBER 15TH WHEN ANOTHER EEG WILL BE DONE. BABY HAS BEEN ON FORMULA AND HAD THE SAME ROUTINE AND DIET IN THE 24 HOURS PRIOR TO THE SEIZURE, PLAYING WITH HIS BOUNCER AND WALKER. THERE IS NO HISTORY ANY COLDS, FEVERS OR RASHES. HIS LAST IMMUNIZATION WAS JUNE 10TH, 2014; HE HAS ALSO RECEIVED REGULAR FLU SHOTS. MOTHER SAID THAT SHE HAD GIVEN THE BABY 3 TABLETS OF TEETHING PRODUCT THE DAY BEFORE THE SEIZURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/02/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
OCT 24 2014

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1571

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/02/14 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY: [signature] DATE: 10-10-14

BY: Eric Bani DATE: 10-10-14
QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

OCT 23 2014

10542775-01-00-04

ANDARD
OPATHIC
HE USA SINCE 1903

Serious Adverse Event
SAE-0048-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/8/14
Date

DSS
OCT 24 2014

OCT 29 2014

Individual Case Safety Report

10542775-01-00-05

Case ID: 10542775

Hyland's®

RSE EVENT DATA FORM

AE #: 1571 COMPLAINT #: 2581

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

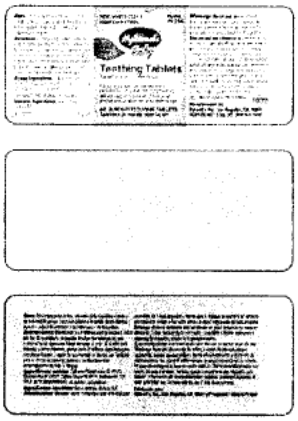
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
OCT 24 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 10-10-14

BY: Eric Bain DATE: 10-10-14
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

OCT 23 2014

Individual Case Safety Report

10542937-01-00-01

CaseID: 10542937

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

e by user-facilities
ributors and manufacturers
IDATORY reporting

OTC

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

Page 1 of 6

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: 10 Months or Date of Birth:	3. Sex ☐ Female ☑ Male	4. Weight ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
08/00/2014	10/06/2014

5. Describe Event or Problem

A MOTHER CALLED AFTER READING ABOUT BELLADONNA AND WONDERED IF IT WAS RELATED TO HER SON'S SEIZURE-LIKE SYMPTOMS. THE SYMPTOMS SEEM TO OCCUR 4 - 5 TIMES A MONTH, SOMETIMES WHEN HE WAS AWAY FROM MOTHER'S HOME. SHE SAYS THAT HE SLEEPS DEEPLY AND IS DIFFICULT TO AROUSE; HE IS SLOW TO RESPOND. HE HAS BEEN HAVING THEM FOR THE LAST 2 MONTHS; DURING THIS TIME HE HAS NOT BEEN TAKING TEETHING TABLETS. HER SON IS 1 YEAR OLD, AND DID TAKE TEETHING TABLETS DURING HIS TEETHING EPISODES FROM 6 MONTHS OF AGE UNTIL 10 MONTHS OLD, SHE JUST USED TEETHING RINGS TO HELP HIM, HAVING "FORGOTTEN" ABOUT THE TABLETS. ON THE PHONE MESSAGE, THE MOTHER REPORTED THAT HER SON HAD SEIZURES AND HAD A "BRAIN BLEED". HE HAS BEEN ON NYSTATIN AND AMOXICILLIN FOR THRUSH, EAR INFECTIONS, COLDS, AND "BACTERIAL STOMACH INFECTIONS", WHICH SHE SAYS SEEMS TO HAVE STARTED AT 6 MONTHS, WHEN HE WAS TEETHING AND STARTED USING TEETHING TABLETS. SHE THOUGHT HE HAD A LOWERED IMMUNE SYSTEM. HE ALSO VOMITED FREQUENTLY DESPITE FORMULA CHANGES, AND WAS DIAGNOSED AS HAVING ACID REFLUX, SHE WAS TOLD THAT THERE WAS NOTHING THAT COULD BE DONE FOR IT. CHILD HAS A HISTORY OF "LOTS

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

DOCTOR HAS SCHEDULED AN MRI IN [illegible] WEEKS (10/22/14)

BLOOD TEST FOR IRON -- WHICH WAS NORMAL

Received
OCT 23 2014
CDR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

GERD; ACID REFLUX;

HISTORY OF BACTERIAL STOMACH INFECTIONS, EAR INFECTIONS, FREQUENT COLDS, THRUSH.

CHILD IS PRONE TO FEVERS AND DEVELOPS THEM AFTER IMMUNICATION SHOTS.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 AS PER LABEL/AS NEEDED	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF OF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

NYSTATIN, AMOXICILLIN, TYLENOL, AND MOTRIN

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Unique Identifier (UDI) #	☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

OCT 23 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

DSC

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

OCT 24 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

Individual Case Safety Report

CaseID: 10542937

10542937-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # _____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code _____ - _____ - _____ Device Code _____ - _____ - _____
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 10/01/2014
5. (A)NDA # _____ IND # _____ BLA # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURE LIKE SYMPTOMS, DEEP SLEEP
9. Manufacturer Report Number: 54973 AE # 1567

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code _____ - _____ - _____ Device Code _____ - _____ - _____ Method _____ - _____ - _____ - _____ Results _____ - _____ - _____ - _____ Conclusions _____ - _____ - _____ - _____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: _____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
OCT 24 2014

OCT 23 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

10542937-01-00-03

...NTINUATION PAGE)
...e by user-facilities,
...ributors, and manufacturers
...for MANDATORY reporting

MEDWATCH

FORM FDA 3500A (2/13) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

OF FEVERS WITH TEETHING". THE HIGHEST FEVER HE ELICITS IS 102F. DURING THE TIME HE WAS GIVEN TEETHING TABLETS, HE WAS ALSO GIVEN TYLENOL, AND LATER MOTRIN FOR FEVER. (MOTRIN WHEN HE WAS OLD ENOUGH.) CHILD HAS BEEN SLEEPING MORE OFTEN THAN USUAL. HIS REGULAR NAPS TEND TO BE 15 MINUTES, BUT LATELY HE HAS BEEN HAVING 4 NAPS A DAY AND ONE DAY SLEPT FOR 4 HOURS.

Back to Item B.5

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

Back to Item B.6

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Back to Item B.7

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish)*

Back to Item C.10

DSS
OCT 24 2014

Back to Item D.11

OCT 23 2014

Other Remarks

10542937-01-00-04

COMPLAINT RECORD

10542937

COMPLAINT #: 2577

DATE OF COMPLAINT: 10/01/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: THREW BOTTLE AWAY

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: A MOTHER CALLED AFTER READING ABOUT BELLADONNA AND WONDERED IF IT WAS RELATED TO HER SON'S SEIZURE-LIKE SYMPTOMS. THE SYMPTOMS SEEM TO OCCUR 4 - 5 TIMES A MONTH, AND SOMETIMES WHEN HE WAS AWAY FROM MOTHER'S HOME. SHE SAYS THAT HE SLEEPS DEEPLY AND IS DIFFICULT TO AROUSE; HE IS SLOW TO RESPOND TO HIS NAME BEING CALLED OR MOTHER WAVING HER ARMS AROUND. HE HAS BEEN HAVING THEM FOR THE LAST 2 MONTHS; DURING THIS TIME HE HAS NOT BEEN TAKING TEETHING TABLETS. HER SON IS 1 YEAR OLD, AND DID TAKE TEETHING TABLETS DURING HIS TEETHING EPISODES FROM 6 MONTHS OF AGE UNTIL 10 MONTHS OLD. AT 10 MONTHS OLD, SHE JUST USED TEETHING RINGS TO HELP HIM, HAVING "FORGOTTEN" ABOUT THE TABLETS. ON THE PHONE MESSAGE, THE MOTHER REPORTED THAT HER SON HAD SEIZURES AND DOCTOR HAD CALLED THEM "BRAIN BLEEDS". BUT SHE DID NOT MENTION THIS ON THE PHONE CALL. HE HAS BEEN ON NYSTATIN AND AMOXICILLIN FOR THRUSH, EAR INFECTIONS, COLDS, AND "BACTERIAL STOMACH INFECTIONS", WHICH SHE SAYS SEEMS TO HAVE STARTED AT 6 MONTHS, WHEN HE WAS TEETHING AND STARTED USING TEETHING TABLETS. SHE THOUGHT HE HAD A LOWERED IMMUNE SYSTEM. HE ALSO VOMITED FREQUENTLY DESPITE FORMULA CHANGES, AND WAS DIAGNOSED AS HAVING ACID REFLUX. SHE WAS TOLD THAT THERE WAS NOTHING THAT COULD BE DONE FOR IT.

CHILD HAS A HISTORY OF "LOTS OF FEVERS WITH TEETHING". THE HIGHEST FEVER HE ELICITS IS 102°F. DURING THE TIME HE WAS GIVEN TEETHING TABLETS, HE WAS ALSO GIVEN TYLENOL AND LATER MOTRIN FOR FEVER. (MOTRIN WHEN HE WAS OLD ENOUGH.) THE DOCTOR HAS SCHEDULED AN MRI FOR OCTOBER 22ND. HIS LAST IMMUNIZATION WAS SEPTEMBER 2. HE DEVELOPS FEVERS AFTER THE SHOTS. HE ALSO HAS BEEN SLEEPING MORE OFTEN THAN USUAL. HIS REGULAR NAPS TEND TO BE 15 MINUTES, BUT LATELY HE HAD BEEN HAVING 4 NAPS A DAY AND ONE DAY SLEPT FOR 4 HOURS. THE ONLY TEST HE HAS RECEIVED TO DATE WAS A BLOOD TEST FOR IRON, WHICH WAS NORMAL.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/01/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: OCT 24 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1567

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/01/14 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY: Rewalt

DATE: 10-10-14 OCT 23 2014

BY: Eric Baer
QA / QC DIRECTOR

DATE: 10-10-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10542937-01-00-05

NDARD
PATHIC
USA SINCE 1903

Serious Adverse Event
SAE-0044-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/8/14
Date

DSS
OCT 24 2014

OCT 23 2014

Individual Case Safety Report

CaseID: 10542937

10542937-01-00-06

Hyland's®

:RSE EVENT DATA FORM

AE #: 1567 COMPLAINT #: 2577

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

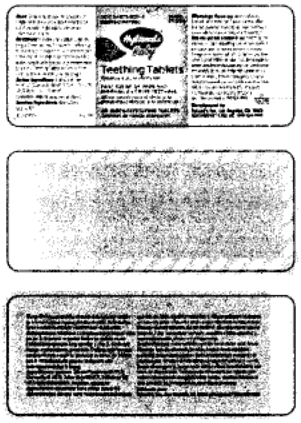
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
OCT 24 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-10-14

BY: QA / QC DIRECTOR DATE: 10-10-14 OCT 23 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

10542971-01-00-01

CaseID: 10542971

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...IC
...e by user-facilities, ...ributors and manufacturers ...DATORY reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

...EDWATCH

FORM FDA 3500A (2/13)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	9 Months	☑ Female	____ lbs
In confidence	or ____ Date of Birth:	☐ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
05/00/2014 & 09/22/2014	10/09/2014

5. **Describe Event or Problem**

MOTHER CALLED CONCERNED ABOUT HER 1 YEARS OLD DAUGHTER WHO HAS BEEN TAKING TEETHING TABLETS AS NEEDED FROM MARCH UNTIL SEPTEMBER 5, 2014. HER DAUGHTER DEVELOPED SYMPTOMS IN MAY (HEAD SWELLING) AND SEPT. 22 (FEBRILE SEIZURE). SHE IS WONDERING IF THEY ARE RELATED TO THE TEETHING TABLETS. THE CT SCAN IN MAY IDENTIFIED THE SWELLING AS "BLEEDING BETWEEN THE SKIN AND SKULL". THERE WAS ANOTHER SWELLING A MONTH OR SO LATER ON ANOTHER PART OF HER HEAD. ALSO, WHEN SHE WAS TEETHING. THE CHILD HAS HAD "WEIRD EPISODES" THAT ARE OUT OF CHARACTER TO HER SUCH AS SCREAMING ON WAKING (AS OF SEPT. 29TH), BANGING AND HOLDING HER HEAD. SHE WAS INTRODUCED TO COW'S MILK ON THE 24TH. ON SEPT. 19TH (OR 22ND AS PER CUSTOMER) CHILD WAS DIAGNOSED WITH A VIRUS AND GIVEN AMOXICILLIN. SHE VOMITTED THAT NIGHT, AND ROLLED HER EYES, WENT STIFF AND STOPPED BREATHING BRIEFLY. THE DOCTOR WHO SAW THE CHILD SEVERAL DAYS LATER DIAGNOSED IT AS FEBRILE SEIZURE.

(Continue on page 3)

6. **Relevant Tests/Laboratory Data, Including Dates**

CT SCAN -- MAY 2014, UL... ...ORK, MRI TEST IS PENDING. ALL NEGATIVE SO FAR.

Received
OCT 23 2014
CDR

(Continue on page 3)

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

EAR INFECTION (SEPT. 2, 2014), FUNGAL INFECTION FROM AMOXICILLIN (SEPT.), KAWASAKI VIRUS (SEPT. 19), FEBRILE SEIZURE (SEPT. 19 OR 22).

LAST IMMUNIZATION: AUGUST 10, 2014

SPRAYED THE GARAGE FOR TERMITES IN SEPTEMBER 2014.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 2 TABLETS ORALLY	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A10014	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC# or Unique ID**: 54973-3127-1

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

AMOXICILLIN, BABY ORAJEL (FEB. 2014 -- HAD A "CHOKING REACTION"), IBUPROFEN AND LATER ADVIL. GAVE ADVIL AFTER SEIZURE.

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** | 2b. **Procode**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Unique Identifier (UDI) #	☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?** ☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

10. **Device Available for Evaluation?** *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)* OCT 23 2014

11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. **Name and Address**

(b) (6)

(b) (6) USA

DSS
OCT 24 2014

Phone #	Email Address
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

10542971-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 10/03/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #:
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SWELLING AND SEIZURE
9. Manufacturer Report Number: 54973 AE # 1574

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
OCT 24 2014

OCT 23 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

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Individual Case Safety Report

10542971-01-00-03

COMPLAINT RECORD

C 10542971

COMPLAINT #: 2584

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 10/03/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A10014 BOTTLE
A10114 BOX

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: MOTHER CALLED CONCERNED ABOUT HER 1 YEAR OLD DAUGHTER WHO HAS BEEN TAKING TEETHING TABLETS AS NEEDED FROM MARCH UNTIL SEPTEMBER 5, 2014. HER DAUGHTER DEVELOPED SYMPTOMS IN MAY (HEAD SWELLING) AND SEPTEMBER 22 (FEBRILE SEIZURE). SHE IS WONDERING IF THEY ARE RELATED TO THE TEETHING TABLETS. THE CT SCAN IN MAY IDENTIFIED THE SWELLING AS "BLEEDING BETWEEN THE SKIN AND SKULL". THERE WAS ANOTHER SWELLING A MONTH OR SO LATER ON ANOTHER PART OF HER HEAD, ALSO WHEN SHE WAS TEETHING. THE CHILD HAS HAD "WEIRD EPISODES" THAT ARE OUT OF CHARACTER TO HER SUCH AS SCREAMING ON WAKING (AS OF SEPTEMBER 29TH), BANGING AND HOLDING HER HEAD. ON SEPTEMBER 19TH (OR 22ND AS PER CUSTOMER) CHILD WAS DIAGNOSED WITH A VIRUS AND GIVEN AMOXICILLIN. SHE VOMITTED THAT NIGHT, AND ROLLED HER EYES, WENT STIFF AND STOPPED BREATHING BRIEFLY. THE DOCTOR WHO ONLY SAW THE CHILD SEVERAL DAYS LATER DIAGNOSED IT AS FEBRILE SEIZURE. THE MOTHER COMMENTED THAT HER OLDER SON HAD SIMILAR SYMPTOMS AND IT WAS DIAGNOSED AS ANGER RELATED. AUGUST 10, 2014 WAS HER LAST IMMUNIZATION. SEPTEMBER 24, 2014 THE CHILD WAS GIVEN MILK FOR THE FIRST TIME.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/03/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS
OCT 24 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1574

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/03/14 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 10-16-14 OCT 23 2014

BY: Eric Baum
QA / QC DIRECTOR

DATE: 10-15-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10542971-01-00-04

CaseID: 10542971

INDARD
OPATHIC
E USA SINCE 1903

Serious Adverse Event
SAE-0051-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lots # A10014 or A10114, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lots' (b) (4) and (b) (4) units respectively have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lots # A10014 and A10114 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lots # A10014 and A10114. Both lots are from the same bulk lot # 122523, which was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0280-2014) has been received for Hyland's Baby Teething Tablets lot # A10014. The complaints were reviewed and the complaints do not appear to be related. No other complaints have been reported related to Hyland's Baby Teething Tablets lot # A100114. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

10/14/14
Date

DSS
OCT 24 2014

OCT 28 2014

CC-0801-2014
AE-0477-2014

10542971-01-00-05

Hyland's

RSE EVENT DATA FORM

AE #: 1574 COMPLAINT #: 2584

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

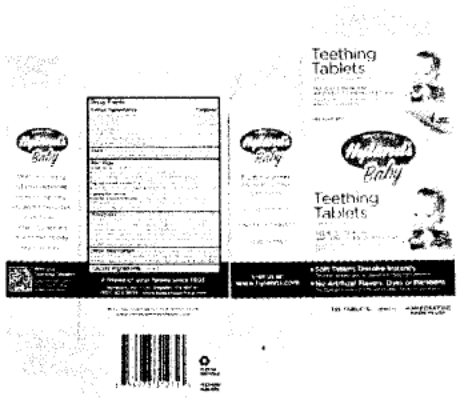
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
OCT 24 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DWatt DATE: 10-16-14

BY: Eric Baum DATE: 10-15-14
QA / QC DIRECTOR

OCT 23 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

10543066-01-00-01

CaseID: 10543066

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...se by user facilities, ...rters and manufacturers ...DATORY reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

FORM FDA 3500A (2/13)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	5 Months or Date of Birth:	☑ Female ☐ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
09/01/2014	10/07/2014

5. Describe Event or Problem

MOTHER WAS CONCERNED THAT HER 5 MONTH OLD BABY'S SEIZURE WAS ASSOCIATED WITH TAKING TEETHING TABLETS, BEGINNING AUGUST 10, 2014. BABY WAS HOSPITALIZED (b) (6) (b) (6) WITH HIGH FEVER (105.6F), SHALLOW BREATHING, ALTERED STATE OF CONSCIOUSNESS, AND A HEART RATE OF 240. A URINARY TRACT INFECTION WAS DISCOVERED THRUGH A URINE TEST AND THE TREATMENT GIVEN WAS RECTAL TYLENOL AND 3 DIFFERENT ANTIBIOTICS INCLUDING BACTRIM. TWO WEEKS PRIOR, THE MOTHER TOOK THE BABY TO THE HOSPITAL BECAUSE SHE WAS "NOT HER USUAL SELF". BABY'S SYMPTOMS INCLUDED DROOLING, NOT SMILING AND A FEVER OF 102.5F.

Received
OCT 23 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

FIRST DIAGNOSIS OF "VIRAL SYNDROME" WAS RECEIVED FROM FIRST HOSPITAL VISIT IN (b) (6) WAS FOR A HIGH FEVER (102F). SECOND VISIT ON (b) (6) WAS FOR A HIGH FEVER (105.6F) AND URINARY TRACT INFECTION, AND SEIZURE. MENINGITIS TEST, BRAIN WAVE SCAN, EPILEPSY TEST, AND BLOOD AND URINE TESTS. DIAGNOSIS WAS A URINARY TRACT INFECTION. URINE TEST SHOWED BACTERIA, THE OTHER TESTS WERE NORMAL.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

LAST IMMUNIZATION WAS IN AUGUST. BABY IS FORMULA FED.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 2 TABS, 2 X DAY, 2-3 DAYS	#1
#2	#2

4. Diagnosis for Use (Indication)

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 A44514	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

TYLENOL, IV FLUIDS, 3 DIFFERENT ANTIBIOTICS INCLUDING BACTRIM FOR UTI.

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

OCT 23 2014

10. Device Available for Evaluation? (Do not send to FDA)

☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

DSS
OCT 24 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

CaseID: 10543066

10543066-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual) Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source (Check all that apply) ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer (mm/dd/yyyy): 10/01/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report (Check all that apply) ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURE
9. Manufacturer Report Number: 54973 AE # 1568

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____
4. Device Manufacture Date (mm/yyyy)
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes (Refer to coding manual) Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

OCT 28 2014

DSS
OCT 24 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

10543066-01-00-03

COMPLAINT RECORD

10543066

COMPLAINT #: 2578

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 10/01/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A44514

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: ON AUGUST 10, 5 MONTH OLD BABY STARTED USING TEETHING TABLETS. (b) (6) THE MOTHER TOOK THE BABY TO THE HOSPITAL BECAUSE SHE WAS NOT HER USUALLY HAPPY SELF, SHE WAS NOT SMILING AND WAS DROOLING, AND HAD A FEVER OF 102.5°F. THE DIAGNOSIS WAS "VIRAL SYNDROME". (b) (6) MOTHER CALLED 911 WHO TOOK HER DAUGHTER TO THE HOSPITAL FOR A HIGH FEVER 105.6°F, SHALLOW BREATHING, PALE FACE, ALTERED STATE, HEART RATE OF 240. SHE WAS TRANSFERRED TO THE PEDIATRIC INTENSIVE CARE UNIT WHERE SHE HAD A SPINAL MENINGITIS TEST, BRAIN WAVE SCAN, EPILEPSY TEST, AND BLOOD AND URINE TESTS. THE DIAGNOSIS WAS A "URINARY TRACT INFECTION". AT THIS TIME MOTHER STOPPED GIVING TEETHING TABLETS. SHE ALSO STOPPED GIVING BANANAS AS SHE HAD INTRODUCTED THEM SHORTLY BEFORE THE SEIZURE EVEN THOUGH THE DOCTOR HAD RULED THEM OUT. BABY WAS GIVEN RECTAL TYLENOL, IV FLUIDS AND 3 DIFFERENT ANTIBIOTICS INCLUDING BACTRIM. A FEW DAYS AFTER BEING SENT HOME, MOTHER RETURNED TO THE HOSPITAL BECAUSE HER DAUGHTER STILL HAD A FEVER. SHE WAS TOLD TO KEEP USING BACTRIM AND TYLENOL. MOTHER RETURNED FOR ANOTHER HOSPITAL VISIT AS HER DAUGHTER HAD DEVELOPED A RASH ON HER WHOLE BODY AS A REACTION TO THE ANTIBIOTIC MEDICATION. THEY STOPPED THE MEDICATION AS THE URINARY INFECTION WAS RESOLVED. MOTHER HAD CALLED THE FDA ASKING IF THE TEETHING TABLETS WERE ON RECALL AFTER READING ABOUT THEM ON FACEBOOK. THEY SAID THE RECALL WAS IN 2010 AND THAT A REFORMULATED PRODUCT WAS BACK ON THE SHELVES. A REPORT WOULD BE SENT FOR HER TO FILL OUT. THE MOTHER COMMENTED THAT IF WE WERE SUBMITTING A REPORT TO THE FDA, THEN SHE WOULD NOT DUPLICATE IT BY SENDING IN ONE AS WELL. DURING THIS TIME, THE BABY HAS NOT YET ERUPTED ANY TEETH EVEN THOUGH THEY SEEM TO BE APPEARING AS WHITE MARKS ON HER GUMS. MOTHER HAS USED TEETHING TABLETS PREVIOUSLY FOR HER OLDER CHILD WITH NO ADVERSE REACTION. LAST NIGHT, THE BABY WAS GIVEN TEETHING TABLETS AGAIN, AND SLEPT THROUGH THE NIGHT. THE MOTHER WAS WORRIED AFTER READING ABOUT TEETHING TABLETS ONLINE THAT THIS MAY NOT BE A GOOD SIGN, EVEN THOUGH IT IS EXPLAINED ON THE LABEL THAT SLEEPING CAN OCCUR AS A SIGN OF RELAXATION. THE BABY RECEIVED HER LAST IMMUNIZATION SHOT IN AUGUST. MOTHER SEEMED QUITE AGITATED AND SAID SHE WOULD PURSUE LEGAL ACTION. SHE WOULD LIKE A REFUND OF $8.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/01/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: OCT 23 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1568

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/01/14 BY: TUTTI GOULD

DSS

SECTION V:

REVIEWED BY MANAGEMENT BY: T C Wolff DATE: 10-10-ici OCT 24 2014

BY: Eric Bain QA / QC DIRECTOR DATE: 10-10-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10543066-01-00-04

'ANDARD
OPATHIC
AE USA SINCE 1903

Serious Adverse Event
SAE-0034-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A44514, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A44514 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A44514. The Baby Teething bulk lot # 123338 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0641-2014) has been received for Hyland's Baby Teething Tablets lot # A44514. The complaints were reviewed and although a previous SAE has been reported related to this bulk lot the complaints do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A44514.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

10/8/14
Date

OCT 23 2014

DSS
OCT 24 2014

CC-0776-2014
AE-0457-2014

10543066-01-00-05

CaseID: 10543066

RSE EVENT DATA FORM

AE #: 1568 **COMPLAINT #:** 2578

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

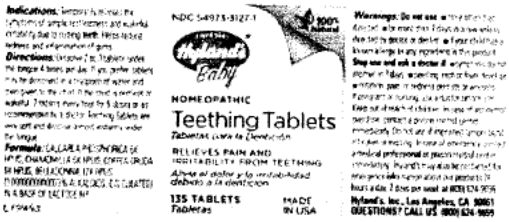
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

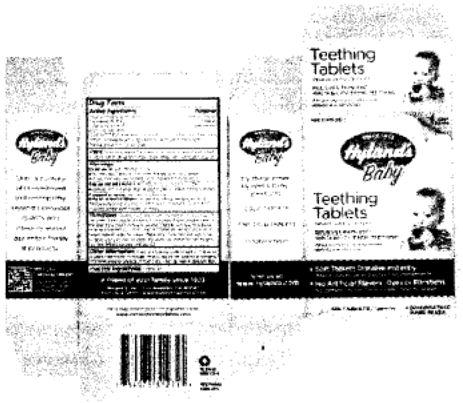
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

OCT 28 2014

REVIEWED BY MANAGEMENT BY: RWelt DATE: 10-13-14

BY: Eric Bain DATE: 10-10-14 DSS
QA / QC DIRECTOR

OCT 24 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE **FORM SAE01**

Individual Case Safety Report

10547547-01-00-01

for use by user-facilities, distributors and manufacturers MANDATORY reporting

CaseID: 10547547

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 1 Years — or Date of Birth:
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: ____ (mm/dd/yyyy)
- ☑ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 01/00/2005 -- PRESENT

4. Date of This Report (mm/dd/yyyy): 10/08/2014

5. Describe Event or Problem

MOTHER POSTED ON (b) (6) THAT 10 YEAR OLD SON HAS MOTOR FUNCTION DELAYS AFTER USE OF TEETHING TABLETS AS AN INFANT. STRUGGLES WITH SPEECH, OT, READING, ATTENTION SPAN, MEMORY AND IS IN A SPECIAL EDUCATION CLASS.

Received
OCT 23 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NO HISTORY OF DEVELOPMENTAL DELAYS IN PARENTS. YOUNGER SISTER ALSO HAD SIMILAR SYMPTOMS AS HER BROTHER.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
- #1 HYLAND'S TEETHING TABLETS
- #2

2. Dose, Frequency & Route Used
- #1 AS DIRECTED ON THE LABEL
- #2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
- #1
- #2

4. Diagnosis for Use (Indication)
- #1 TEMP RELIEF OF TEETHING PAIN
- #2

5. Event Abated After Use Stopped or Dose Reduced?
- #1 ☐ Yes ☑ No ☐ Doesn't Apply
- #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
- #1
- #2

7. Exp. Date
- #1
- #2

8. Event Reappeared After Reintroduction?
- #1 ☐ Yes ☐ No ☑ Doesn't Apply
- #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Unique Identifier (UDI) #

5. Operator of Device
- ☐ Health Professional
- ☐ Lay User/Patient
- ☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

USA

DSS
OCT 24 2014

Phone #

Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☑ Unk.

OCT 23 2014

Individual Case Safety Report

10547547-01-00-02

FDA USE ONLY

User Facility ☐ Importer ☐

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address:
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/04/2014

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
DEVELOPMENTAL AND MOTOR FUNCTION DELAYS

9. Manufacturer Report Number
54973 AE # 1572

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Ty pe?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

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OCT 23 2014
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This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report CUSTOMER COMPLAINT RECORD

10547547-01-00-03

10547547

COMPLAINT #: 2582

DATE OF COMPLAINT: 10/04/14

PRODUCT: HYLAND'S TEETHING TABLETS

ITEM CODE: TEET

SIZE: UNKNOWN

LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (b) (6) ON (b) (6) I JUST FOUND OUT THAT THESE TABLETS WERE VOLUNTARILY RECALLED BY THE HYLAND'S COMPANY IN 2010. THEN AFTER THEY PUT A CHILD RESISTANT LID ON THEIR PRODUCT PUT IT BACK ON THE SHELVES. THIS PRODUCT CONTAINS AN INGREDIENT CALLED BELLADONNA. NOW TO THOSE OF YOU WHO DO NOT KNOW WHAT BELLADONNA IS HERE IS A DESCRIPTION CEN.M.WIKIPEDIA.ORG/WIKI/ATROPA_BELLADONNA. IT IS THE MOST TOXIC PLANT IN THE NORTHERN HEMISPHERE. ANY YET WE HAVE BEEN GIVING THIS TO OUR BABIES!!! I DON'T BELIEVE EVERYTHING I SEE ONLINE BUT THIS IS ONE I FOUND I NEEDED TO RESEARCH. MY SON WAS BORN IN 2004 I WAS TOLD ABOUT THESE AMAZING TEETHING TABLETS FROM A FRIEND. I USED THEM FOR ALL 3 OF MY KIDS. NOW MY 2 OLDER CHILDREN NOW AGES 10 AND 6 BOTH HAVE THE SAME EXACT MOTOR FUNCTION DELAYS. BOTH SPEECH AND OT BOTH HAVING TO DO WITH THE BRAIN. NOW I AM NOT SAYING THAT THESE TABLETS ARE DEFINITELY THE CAUSE OF THEIR DELAYS BUT IT SEEMS PRETTY ODD THAT THEY WERE BORN COMPLETELY HEALTHY AND NEVER HAD ANY PROBLEMS UNTIL AFTER THEIR FIRST BIRTHDAYS. MY OLD DAUGHTER DID NOT TALK UNTIL SHE WAS 3 AND EVEN THEN SHE ONLY HAD AROUND 40 WORDS MY SON HAD BEEN STRUGGLING WITH SPEECH, OT, READING, ATTENTION SPAN, MEMORY AND A LOT MORE. THE THING THAT GETS ME IS THAT THEY HAVE THE SAME EXACT SYMPTOMS. WHAT ARE THE ODDS?? I USED THESE TABLETS AS DIRECTED FOR BOTH OF THEM EVERYDAY WHILE THEY WERE TEETHING. FOR MONTHS AT A TIME. THEY SEEMED TO WORK GREAT!!! I NEVER THOUGHT THAT THERE WOULD BE PROBLEMS LATER ON. THE BOTTLE SAYS HOMEOPATHIC. THAT'S GOOD RIGHT? WRONG. HOMEOPATHIC DOES NOT MEAN SAFE! I KNOW THAT NOW. MY SON IS 10 AND IS A SPECIAL EDUCATION CLASS. HE STRUGGLES CONSTANTLY WITH EVERYTHING. HE HAD THESE TABLETS ON A DAILY BASIS FROM THE AGE OF 9 *(CONTINUED ON NEXT PAGE)*

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/04/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1572

DSS

OCT 24 2014

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/04/14 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 10-14-14

BY: QA / QC DIRECTOR DATE: 10-14-14

cc: QA / QC Production
Packaging Shipping / Receiving

OCT 23 2014

Form # VD1

NATURE OF COMPLAINT (CONT):

MONTHS UNTIL HE WAS FINISHED TEETHING. HE WAS MY FIRST BABY. AND ANYONE WHO HAS MORE THAN ONE CHILD KNOWS HOW PARANOID YOU ARE WITH YOUR FIRST. I WAS SCARED TO USE THE TABLETS AT FIRST. BUT MY HUSBAND TRIED THEM WHEN I WAS NOT HOME AND THEY WORKED. THEY MADE A SCREAMING BABY CALM DOWN AND BE PAIN FREE. LEARNING ALL OF THE NEW NEWS I'M HEARING ABOUT THESE TABLETS IS REALLY SCARING ME. ESPECIALLY WITH THE WAY MY CHILDREN ARE. NO KNOWN CAUSE. DOESN'T RUN IN THE FAMILY. PARENTS NEVER HAD DELAYS OR ANY PROBLEMS GROWING UP. I WANT TO REACH OUT TO OTHER PARENTS WHO HAVE USED THESE TABLETS. I WANT TO KNOW ABOUT YOUR CHILDREN'S SYMPTOMS IF ANY. ANY INFORMATION WILL HELP ME MAKE A POSSIBLE CASE AGAINST THIS COMPANY AND TO WARN POISONOUS PLANT EXTRACTS IN THE WORLD. PLEASE RE-THINK GIVING YOUR BABIES THESE TABLETS. I WISH I KNEW ALL THIS INFORMATION YEARS AGO. IT WOULD HAVE SAVED ME COUNTLESS YEARS OF ANGUISH. PLEASE COMMENT IF YOU HAVE SEEN ANY SYMPTOMS IN YOUR BABY OR CHILDREN. I WILL BE MAKING A FB PAGE AND WILL POST THE LINK HERE IF YOU WOULD LIKE TO JOIN TO BE UPDATED OF ANY FINDINGS.

HYLAND'S POSTED ON FACEBOOK ON 10/06/14: HYLAND'S IS COMMITTED TO FOLLOWING UP ON REPORTS OF ADVERSE EVENTS AND WOULD ASK YOU TO PLEASE CONTACT OUR PRODUCT INFORMATION SERVICE AS SOON AS POSSIBLE AT 1-800-624-9659 EXT. 4117 TO DISCUSS WHAT HAPPENED WITH YOUR CHILD AND FOR MORE INFORMATION ABOUT THE PRODUCT. AS A GENERAL GUIDELINE, WE ENCOURAGE ALL CONSUMERS TO CONTACT COMPANIES BY PHONE AT THE NUMBER PROVIDED RATHER THAN POSTING ON (b) (6) WHEN THEY ARE CONCERNED ABOUT A REACTION TO A MEDICINE SO THAT ANY ISSUES CAN BE PROPERLY ADDRESSED. PLEASE KNOW THAT HYLAND'S BABY TEETHING TABLETS HAVE A VERY WIDE MARGIN OF SAFETY, AS DO ALL HOMEOPATHICALLY-PREPARED MEDICINES.

Individual Case Safety Report

10547547-01-00-05

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us Adverse Event
AE-0049-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/10/14
Date

DSS
OCT 24 2014

OCT 23 2014

Individual Case Safety Report

10547547-01-00-06

ID: 10547547

Hyland's

US ADVERSE EVENT DATA FORM

AE #: 1572 COMPLAINT #: 2582

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
OCT 24 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-14-14

OCT 23 2014

BY: QA / QC DIRECTOR DATE: 10-14-14

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 10567790

10567790-01-00-01

...mer Report

...Y reporting of
...uct problems and
product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 571145

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	14 Months (b) (6)	☑ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/31/2014	11/04/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

CTU
NOV 05 2014

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hylands teething tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/30/2014 - 10/31/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

6. Lot #	7. Expiration Date
#1 A69614	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
54973-3127-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

NOV 5 2014

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: (b) (6)
Address:
City: State: -- ZIP:

Phone #	E-mail
	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

I gave my daughter two tablets of Hylands Teething tablets on Thursday, 10/30/14 and three on Friday 10/31. Friday evening while trick or treating she was being held and began to stare off into space for about 1-2 minutes. We called her name, rubbed her cheek, etc. but could not get her attention. We were worried and took her home immediately. The following morning, 11/1, my husband noticed another similar episode. I called the pediatrician and she is being seen this week. In the meantime she is no longer being given these tablets. She has not had an episode of possible absence seizures since Saturday morning. The only other thing that was odd is that she became very constipated this weekend.

Individual Case Safety Report

10567790-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:White
Medical Conditions: None

Allergies: None

Important Information: None

RX Meds: None

OTC Meds: Occasional Motrin and Tylenol for teething

Individual Case Safety Report

10567790-01-00-03

CaseID: 10570064

10570064-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statem ent on reverse.

e by user-facilities,
ibutors and manufacturers
DATORY reporting

OTC

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (2/13)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	2 Years	☐ Female	____ lbs
In confidence	or ____ Date of Birth:	☑ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
01/29/2013	10/22/2014

5. Describe Event or Problem

THE REPORTER'S SON BEGAN EXPERIENCING SEIZURES WITH VOMITING DURING THE PERIOD OF TIME THAT HE WAS TAKING THE "BABY TEETHING TABLETS" PRODUCT. HE EXPERIENCED 4 SEIZURES BETWEEN (b) (6) AND 06/2013.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(b) (6) VARIOUS TESTS, INCLUDING AN EEG -- ALL RESULTS WERE NORMAL.

DOCTOR'S SAW EVIDENCE ON AN EEG THAT CHILD HAD A SEIZURE. NO DIAGNOSIS WAS GIVEN AND A CAUSE FOR THE SEIZURES WAS NOT DETERMINED.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO FAMILY HISTORY OF SEIZURES. CHILD NOT TAKING MEDICATIONS OR SUPPLEMENTS AT THE TIME OF THE ADVERSE EVENTS OTHER THAN THE "TEETHING TABLETS".

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 2-3 TABLETS BY MOUTH QID	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

PLEASE TYPE OR USE BLACK INK

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10570064-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person
5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address:
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other: ____

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 10/21/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURES, VOMITING

9. Manufacturer Report Number: 54973 AE # 1575

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
NOV 05 2014
06

NOV 05 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 10570064

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: 2585

TAKEN BY: (b) (6)

DATE OF COMPLAINT: 10/21/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: THE REPORTER STATED THAT SHE HAD BEEN GIVING HER SON THE "BABY TEETHING TABLETS" PRODUCT LAST YEAR. SHE STATED THAT HE HAD 3 OR 4 SEIZURES DURING THE TIME THAT HE WAS TAKING THE "TEETHING TABLETS". SHE STATED THAT HER SON WAS ALMOST 2 YEARS OLD AT THE TIME. PER THE REPORTER, HER PARENTS CALLED AN AMBULANCE LAST YEAR WHEN HER SON HAD THE FIRST SEIZURE; SHE STATED THAT HE WAS RUSHED TO THE HOSPITAL AND THAT ALL OF HIS TESTS, INCLUDING AN EEG, WERE NORMAL. PER THE REPORTER, THE CHILD WAS ALSO SEEN BY A SPECIALIST AT THE CHILDREN'S HOSPITAL FOLLOWING THE EMERGENCY ROOM VISIT. PER THE REPORTER, THE DOCTORS STATED THAT THERE WAS EVIDENCE ON THE EEG THAT HER SON HAD HAD A SEIZURE, BUT THE DOCTORS WERE UNABLE TO DETERMINE A CAUSE FOR THE SEIZURES. PER THE REPORTER, THE CHILD WAS NEVER GIVEN A DIAGNOSIS. THE REPORTER STATED THAT SHE HAD BEEN GIVING THE CHILD THE "TEETHING TABLETS" ALMOST ON A DAILY BASIS AND THAT SHE HAD USED APPROXIMATELY THREE BOTTLES OF "TEETHING TABLETS" WHILE HER SON WAS TEETHING. SHE STATED THAT SHE GAVE HIM 2 – 3 TABLETS PER DOSE MAINLY WHEN SYMPTOMS WERE PRESENT. SHE STATED THAT SHE FOLLOWED THE RECOMMENDED DOSING INSTRUCTIONS ON THE LABEL AND DID NOT GIVE HIM MORE THAN THE RECOMMENDED DOSE. SHE STATED THAT THE SEIZURES DID NOT OCCUR IMMEDIATELY FOLLOWING A DOSE OF "TEETHING TABLETS", BUT THAT THEY OCCURRED DURING THE PERIOD OF TIME THAT THE CHILD WAS TAKING THE "TEETHING TABLETS." SHE STATED THAT HE WAS NOT TAKING ANY OTHER MEDICATIONS OR SUPPLEMENTS AT THE TIME. PER THE REPORTER THE SEIZURES STOPPED WHEN SHE STOPPED GIVING HER SON THE "TEETHING TABLETS." THE REPORTER STATED THAT SHE RECENTLY SAW A POST ONLINE WHICH SAID THAT THE "BABY TEETHING TABLETS" CAUSE SEIZURES – THIS POST WAS THE REASON THAT SHE CALLED. SHE STATED THAT SHE ALSO SAW ONLINE THAT THIS PRODUCT HAS BEEN RECALLED BECAUSE IT CAUSES SEIZURES. THE REPORTER STATED THAT IF THESE POSTS ARE TRUE, SHE IS READY TO GET HER ATTORNEY INVOLVED BECAUSE OF ALL OF THE TIME AND MONEY THAT THEY SPENT ON DOCTOR'S VISITS FOR HER SON. THE REPORTER STATED THAT SHE HAS A 1 YEAR OLD DAUGHTER, WHO IS HAVING DIFFICULT TEETHING, BUT SHE IS AFRAID TO GIVE HER DAUGHTER THE "TEETHING TABLETS," AND SHE THREW AWAY THE BOTTLE. SHE ASKED IF WE HAD ANY OTHER PAIN PRODUCTS THAT SHE COULD GIVE TO HER DAUGHTER INSTEAD. THE REPORTER STATED THAT SHE WOULD LIKE A REFUND FOR THE BOTTLE THAT SHE BOUGHT FOR HER DAUGHTER; SHE PAID ABOUT $ 8.00 FOR BTET----T135. 10/21/14 FOLLOW-UP EF: SEIZURES OCCURRED DURING THE TIME THAT CHILD WAS TEETHING. ONLY THING DIFFERENT THE MOTHER WAS DOING WAS THAT SHE WAS GIVING THE TEETHING TABLETS DURING THIS TIME. CHILD DID NOT HAVE A FEVER BUT WAS VOMITING DURING THE SEIZURES. SEIZURES OCCURRED THE BEGINNING OF 2013 – THE AMBULANCE TOOK THE CHILD THE (b) (6) DATE OF 1ST SEIZURE) AND AFTER THAT HE HAD 3 MORE SEIZURES AND NOW THEY HAVE RESOLVED. HIS LAST SEIZURE WAS JUNE 2013. NO FAMILY HISTORY OF SEIZURES. WENT TO A SPECIALIST AND THE TESTS WERE NORMAL AND THERE WAS NO SPECIFIC SEIZURE TYPE GIVEN. CHILD WAS 1 ½ YEARS AT THE TIME OF THE SEIZURES. I TOLD THE MOTHER THAT THERE IS NO CONCLUSIVE EVIDENCE THAT BABY TEETHING TABLETS CAUSE SEIZURES, AND THAT IT IS POSSIBLE THAT HER CHILD COULD HAVE BEEN SENSITIVE OR ALLERGIC TO AN INGREDIENT IN THE TABLETS OR THE SYMPTOMS COULD HAVE BEEN DUE TO SOMETHING ELSE SUCH AS ILLNESS OR OTHER MEDICAL REASON.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/21/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1575

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/21/14

BY: (b) (6)

DSS
NOV 05 2014

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 10-29-14

BY: Eva Bann
QA / QC DIRECTOR

NOV 05 2014 10-29-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

Individual Case Safety Report
10570064-01-00-03

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0052-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirteen (113) Adverse Events (AE) which also included thirty-three (33) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/28/14
Date

Individual Case Safety Report

10570064-01-00-04

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NOV 06 2014

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NOV 05 2014

CC-0861-2014
AE-0512-2014

CaseID: 10570064

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1575 COMPLAINT #: 2585

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #:

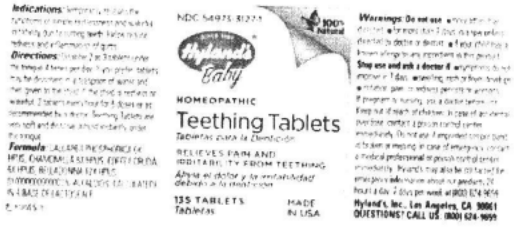
E-MAIL:

Individual Case Safety Report

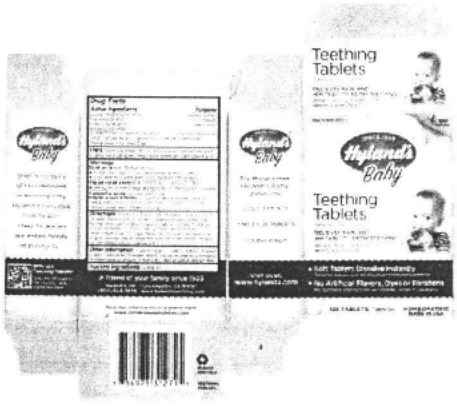
10570064-01-00-05

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWatt DATE: 10-29-14

BY: Eric Baun DATE: 10-29-14
QA / QC DIRECTOR

NOV 05 2014

DSS

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM [illegible] NOV 05 2014
06

CaseID: 10576562

Individual Case Safety Report

10576562-01-00-01

Report OTC

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Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

1/4

FDA USE ONLY
Triage unit sequence # 571660

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	4 Years (b) (6)	☑ Female ☐ Male	50 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/17/2014	11/07/2014

5. **Describe Event, Problem or Product Use Error**
See page 2 for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**
See page 3 for complete text.

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
#1 Name: hylands teething gel and tablets
Strength: as needed
Manufacturer: hylands teething gel and tablets
#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 10/15/2014 - 10/17/2014
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 Tooth pain
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**
2. **Common Device Name**
3. **Manufacturer Name, City and State** CTU

NOV 10 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
(b) (6)

SS

NOV 10 2014

Phone #	E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

noticed a possible connection to using Hylands teething tablets and teething gel my daughter has had a couple fainting spells or seizures with the last one being classified as a seizure after using Hyland's teething tabs and teething gel 2 days in a row for tooth discomfort she was hospitalized at the (b) (6) Children's Hospital for 2 days under observation we were advised not to use those products anymore

Individual Case Safety Report

10576562-01-00-02

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

all tests were done on (b) (6) at the door and (b) (6) Children's Hospital her level seems fine but they said some of those could have been out of her system by the time they took the lab workthey also don't check for belladonna toxicity

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:Other
Medical Conditions: None

Allergies: None

Important Information: None

RX Meds: None

OTC Meds: D3

Individual Case Safety Report

10576562-01-00-04

Individual Case Safety Report

10584800-01-00-01

CaseID: 10584800

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

OTC

...se by user-facilities, ...tributors and manufacturers
...NDATORY reporting

Page 1 of 5

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: Years or Date of Birth:	3. Sex ☐ Female ☑ Male	4. Weight ___ lbs or ___ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ___ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/00/2014	11/03/2014

5. Describe Event or Problem

THE ACTUAL WORDING OF THE E-MAIL WAS VERY GENERAL. THE PERSON STATED "MY SON WAS TEETHING AND I BOUGH YOUR HYLANDS TEETHING TABLETS NOW HE IS HAVING TROUBLE BREATHING AND HES TURNING PALE."

Received
NOV 13 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ___ *(mm/dd/yyyy)*

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NOV 14 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

USA
NOV 13 2014

Phone #	Email Address
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

10584800-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: EDYTA FRACKIEWICZ

Address:

HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 10/19/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #:

7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): TROUBLE BREATHING, PALLOR

9. Manufacturer Report Number: 54973 AE # 1576

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
NOV 14 2014

NOV 18 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
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10584800-01-00-03

COMPLAINT RECORD

Ca[illegible]584800

COMPLAINT #: 2586

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 10/19/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL ON OCTOBER 19, 2014: MESSAGE: I AM WRITING TO ACTUALLY COMPLAIN ABOUT YOUR PRODUCT. MY SON WAS TEETHING AND I BOUGHT YOUR HYLAND'S TEETHING TAB-LETS NOW HE IS HAVING TROUBLE BREATHING AND HE'S TURNING PALE. I WANT A FULL REFUND. AND YOU NEED TO RE-THINK YOUR PRODUCT. CUSTOMER DID NOT RESPOND TO OUR E-MAIL. THE WOMAN ANSWERING THE PHONE NUMBER STATES THAT IT IS A WRONG NUMBER. NO CONTACT INFORMATION PROVIDED FOR REFUND.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/19/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS
NOV 14 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1576

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/19/14 BY: EDYTA FRACKIEWICZ

SECTION V:

NOV 13 2014

REVIEWED BY MANAGEMENT BY: R Wolf DATE: 10-29-14

BY: Eric Bain QA / QC DIRECTOR DATE: 10-29-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10584800-01-00-04

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0053-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirteen (113) Adverse Events (AE) which also included thirty-three (33) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/28/14
Date

DSS
NOV 14 2014

NOV 18 2014

Individual Case Safety Report

10584800-01-00-05

CaseID: 10584800

Hyland's

RSE EVENT DATA FORM

AE #: 1576 **COMPLAINT #:** 2586

SECTION I: **PATIENT INFORMATION** *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE:

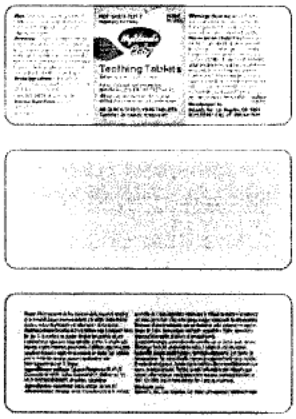
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
NOV 14 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-29-14

BY: QA / QC DIRECTOR DATE: ~~10-29-14~~

NOV 18 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

10589980-01-00-01

CaseID: 10589980

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

umer Report

Y reporting of
uct problems and
product use errors

Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	572474

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	7 Months (b) (6)	☐ Female ☑ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/26/2014	11/15/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

CTU
NOV 17 2014

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hylands teething tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 1-2 dissolvable pills a day	Once daily	Taken under the tongue
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 09/24/2014 – 11/01/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 teething pain/irritabilty
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
54973-3127-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
NOV 17 2014

Phone #	E-mail
	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

My son began using Hylands Teething tablets in Sept 2014. He began to develop extremely high fevers, dry skin, seizures, anemia, vomiting and urinary retention. It took 2 months of many tests and hospital visits to realize it was the belladonna causing all the problems. He has not taken any tablets in 2 weeks and is a new child. He is only 7 months old and NEVER had more than 3 tablets a day. We are still doing testing to see if any permanent damage has been done.

Individual Case Safety Report

10589980-01-00-02

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

chest xrays, blood cultures, CBC, CMP, UA

Individual Case Safety Report

10589980-01-00-03

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:Hispanic/Latino
Medical Conditions: none

Allergies: none

Important Information:

RX Meds:

OTC Meds: iron

Individual Case Safety Report

10589980-01-00-04

Individual Case Safety Report

10601392-01-00-01

CaseID: 10601392

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...r use by user-facilities, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 12 Months — or Date of Birth:
3. Sex: [x] Female [ ] Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- [ ] Death: ____ (mm/dd/yyyy)
- [ ] Disability or Permanent Damage
- [ ] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [x] Hospitalization - initial or prolonged
- [x] Other Serious (Important Medical Events)
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 11/01/2014

4. Date of This Report (mm/dd/yyyy): 11/05/2014

5. Describe Event or Problem

THE REPORTER STATED THAT HIS 1 YEAR OLD DAUGHTER HAS BEEN EXPERIENCING SEIZURES WHILE USING THE "BABY TEETHING TABLETS" PRODUCT. SHE BEGAN USING THE "TEETHING TABLETS" WHEN SHE WAS 6 MONTHS OLD. WHEN SHE WAS 7 MONTHS OLD, SHE HAD 3 SEIZURES IN 1 DAY AND WAS HOSPITALIZED FOR 3.5 DAYS. THE DIAGNOSIS AT THAT TIME WAS: "FEBRILE SEIZURES". THE USE OF THE "TEETHING TABLETS" WAS DISCONTINUED FOR 5 MONTHS. USE BEGAN AGAIN ABOUT 3 WEEKS AGO. ON (b) (6) THE CHILD HAD ANOTHER SEIZURE AND WAS HOSPITALIZED OVERNIGHT. PER THE REPORTER, THE DOCTORS COULD NOT DETERMINE A CAUSE FOR THE SEIZURES AT THAT TIME AND ORDERED AN EEG TO BE PERFORMED IN A COUPLE OF WEEKS.

Received
NOV 19 2014

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

CDR

CT SCAN -- NORMAL RESULTS
EEG ORDERED AND WILL BE DONE IN 2 WEEKS.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NO FAMILY HISTORY OF SEIZURES. NO KNOWN ALLERGIES. CHILD HAS ACID REFLUX.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2TABS BID-QID AS NEEDED
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [x] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1 A52014
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [x] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID
54973-3127-3

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
RANITIDINE SINCE CHILD WAS 1 WEEK OLD.

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
2b. Procode
3. Manufacturer Name, City and State
4. Model #
Lot #
Catalog #
Expiration Date (mm/dd/yyyy)
Serial #
Unique Identifier (UDI) #
5. Operator of Device
[ ] Health Professional
[ ] Lay User/Patient
[ ] Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
NOV 20 2014

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)
(b) (6) USA

NOV 19 2014

Phone # (b) (6)
Email Address

2. Health Professional? [ ] Yes [x] No
3. Occupation: NA
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [x] Unk.

CaseID: 10601392

Individual Case Safety Report

10601392-01-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home
☐ Nursing Home ☐ Ambulatory Surgical Facility
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 11/04/2014

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURES

9. Manufacturer Report Number: 54973 AE # 1577

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Ty pe?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or **11.** ☐ Corrected Data

DSS
NOV 20 2014

NOV 19 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

STANDARD Individual Case Safety Report

CUSTOMER COMPLAINT RECORD

Ca[illegible]601392

10601392-01-00-03

COMPLAINT #: 2587

DATE OF COMPLAINT: 11/04/14

[illegible] TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABLETS

LOT NO.: A52014

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: THE REPORTER STATED THAT HIS 1 YEAR OLD DAUGHTER HAD BEEN EXPERIENCING SEIZURES WHILE USING THE "BABY TEETHING TABLETS" PRODUCT. HE STATED THAT SHE BEGAN TAKING THE PRODUCT WHEN SHE WAS JUST OVER 6 MONTHS OLD. PER THE REPORTER, SHE WAS GIVEN 2 TABLETS AT A TIME 2 – 4 TIMES PER DAY, WHEN SYMPTOMS WERE PRESENT. THE REPORTER STATED THAT SHE WAS NOT GIVEN THE "TEETHING TABLETS" DAILY, BUT WAS TAKING THEM EVERY OTHER DAY AT MOST. PER THE REPORTER, WHEN SHE WAS 7 MONTHS OLD, SHE HAD 3 SEIZURES IN THE SAME DAY. THE REPORTER STATED THAT SHE HAD BEEN CRAWLING, AND THEN SHE COLLAPSED AND WAS UNCONSCIOUS. THE REPORTER DESCRIBED HER AS BEING "LIMP" AND NOT BREATHING, AND HE STATED THAT HER "EYES WERE ROLLING BACK IN HER HEAD." HE STATED THAT CPR WAS ADMINISTERED TO HIS DAUGHTER. AT THAT TIME, SHE WAS TAKEN TO THE HOSPITAL AND WAS ADMITTED FOR 3.5 DAYS. PER THE REPORTER, THE DIAGNOSIS AT THAT TIME WAS "FEBRILE SEIZURES". PER THE REPORTER, FOR THE NEXT 5 MONTHS, HIS DAUGHTER DID NOT HAVE ANOTHER SEIZURE AND THE USE OF THE "BABY TEETHING TABLETS" WAS DISCONTINUED. THE REPORTER STATED THAT HIS DAUGHTER BEGAN TAKING THE "BABY TEETHING TABLETS" AGAIN ABOUT 3 WEEKS AGO. ON (b) (6) SHE HAD ANOTHER SEIZURE AND WAS HOSPITALIZED OVERNIGHT. PER THE REPORTER, THE DOCTORS DID NOT FIND A CAUSE FOR THE SEIZURES AND HAVE ORDERED AN EEG, WHICH THE CHILD WILL HAVE IN A COUPLE OF WEEKS. PER THE REPORTER, THE CHILD TOOK A 30 – 35 MINUTE NAP FOLLOWING A DOSE OF THE "TEETHING TABLETS" ON (b) (6) AND APPROXIMATELY 5 – 7 MINUTES AFTER SHE AWOKE, SHE BEGAN SHAKING AND GASPING FOR AIR. PER THE REPORTER, THE CHILD HAD A FEVER OF 100.1 °F ON (b) (6) PER THE REPORTER, THE CHILD HAD A CT SCAN WITH NORMAL RESULTS. PER THE REPORTER, THE CHILD HAS NOT HAD AN EEG YET, BUT WILL HAVE ONE IN A COUPLE OF WEEKS. PER THE REPORTER, THE CHILD HAS NO KNOWN ALLERGIES AND HAS NO OTHER HEALTH ISSUES, OTHER THAN ACID REFLUX. PER THE REPORTER, THE CHILD HAS BEEN TAKING RANITIDINE FOR ACID REFLUX SINCE THE AGE OF 1 WEEK, AND THE REPORTER STATED THAT SHE HAS NEVER HAD A PROBLEM WITH IT. PER THE REPORTER, THERE IS NO FAMILY HISTORY OF SEIZURES ON EITHER SIDE OF THE CHILD'S FAMILY. THE REPORT STATED THAT THE CHILD HAS A PEDIATRICIAN APPOINTMENT TOMORROW. THE REPORTER STATED THAT IT WOULD BE OK TO CONTACT HIM FOR FURTHER INFORMATION.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: Please see attached investigation report.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/04/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: **CORRECTIVE ACTION:**

DSS

NOV 20 2014

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1577

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/04/14 BY: (b) (6)

SECTION V:

NOV 19 2014

REVIEWED BY MANAGEMENT BY: RWalt DATE: 11-10-14

BY: Eric Brenn QA / QC DIRECTOR DATE: 11-07-14

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

Individual Case Safety Report

10601392-01-00-04

STANDARD OMEOPATHIC
DE IN THE USA SINCE 1903

erious Adverse Event
SAE-0054-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A52014, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A52014 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A52014. The Baby Teething bulk lot # 121976 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints has been received for Hyland's Baby Teething Tablets lot # A44514.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A52014.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

11-7-14
Date

DSS
NOV 20 2014

NOV 19 2014

CC-0920-2014
AE-0545-2014

STANDARD
Individual Case Safety Report

10601392-01-00-05

CaseID: 10601392

Hyland's

VERSE EVENT DATA FORM

AE #: 1577

COMPLAINT #: 2587

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

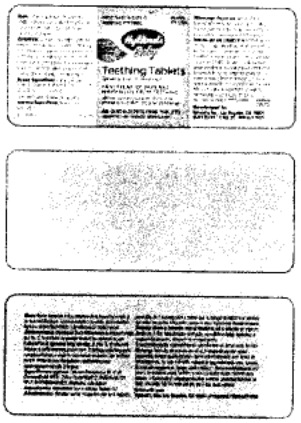
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
NOV 20 2014

SECTION IV:

NOV 19 2014

REVIEWED BY MANAGEMENT BY: RWall DATE: 11-10-14

BY: Eric Brin QA / QC DIRECTOR DATE: 11-07-14

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 10619563

10619563-01-00-01

r CDER

reporting of
problems and
rrors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 573998

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	14 Months (b) (6)	☐ Female ☑ Male	22 lb or kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
11/14/2014	11/26/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hyland's Baby Teething Tablets
Strength: n/a
Manufacturer: Hylands Inc

DSS

#2 Name:
Strength:
Manufacturer:

DEC 01 2014

2. Dose or Amount	Frequency	Route
#1 2	Three times daily	Taken by mouth
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 11/12/2014 - 11/12/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 My son had a tooth coming in.
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1 08/06/2014
#2	#2

9. NDC # or Unique ID
54973-3127-3

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

DEC - 1 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

My son who is 14 months old, was taking Hyland's Baby Teething tablets on (b) (6) My son had 3 seizures within that 24 hour period. He was admitted and was kept for 4 days. I at first did not think anything about the teething tablets causing the seizures. It was then when I researched and realized I was not the only parent that has had the same/similar issue. We have since stopped administering the teething tablets.

Individual Case Safety Report

10619563-01-00-02

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

EEG- Normal (b) (6) MRI- Normal (b) (6) The Doctor at (b) (6) Children's Hospital could not figure out what had caused my son to have the 3 seizures.

Individual Case Safety Report

10619563-01-00-03

e, hepatic/renal dysfunction, etc.) (continued)

B.7. Other Relevant History, Inc

Race:White
Medical Conditions: N/A

Allergies: n/A

Important Information: N/A

RX Meds: None

OTC Meds: Children's Acetaminophen for fever.

Individual Case Safety Report

10619580-01-00-01

ner Report CDER

CaseID: 10619580

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

r reporting of
ct problems and
errors

FDA USE ONLY
Triage unit sequence # 574014

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	5 Months (b) (6)	☑ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	11/24/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Teething tablet
Strength: Julian teething tablets
Manufacturer:

DSS

#2 Name:
Strength:
Manufacturer:

DEC 01 2014

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name CTU

3. Manufacturer Name, City and State DEC - 1 2014

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

My infant had seizure believed to be a direct result of the teething tablets

Individual Case Safety Report

10619580-01-00-02

Individual Case Safety Report

10619580-01-00-03

e, hepatic/renal dysfunction, etc.) (continued)

B.7. Other Relevant History, Inc

Race:White
Medical Conditions: None

Allergies:

Important Information:

RX Meds:

OTC Meds:

CaseID: 10627664

10627664-01-00-01

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product use errors 13

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 574456

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	2 Years (b) (6)	☐ Female ☑ Male	30 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
05/01/2014	12/02/2014

5. **Describe Event, Problem or Product Use Error**
See page 2 for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 2 for complete text.

CTU
DEC 03 2014

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
#1 Name: hyland babt teething tablets
Strength:
Manufacturer: hylands

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2	Four times daily	Taken by mouth
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 04/24/2014 - 04/28/2014
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 Teething
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**
54973-3127-1

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. **If Implanted, Give Date** *(mm/dd/yyyy)* 7. **If Explanted, Give Date** *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
(b) (6)

DSS
DEC 03 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

Gave my son the right dose and a couple of days after he had a seizure

Individual Case Safety Report

10627664-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:White
Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds:

Individual Case Safety Report

10627664-01-00-03

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CaseID: 10631888

10631888-01-00-01

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Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

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product use errors

FDA USE ONLY
Triage unit sequence # 574457

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	18 Months	☐ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☑ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	12/02/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

CTU
DEC 03 2014

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hyland teething tablets
Strength:
Manufacturer: Hyland
#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething pain for babies
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

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PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

DEC 03 2014

B.5. Describe Event or Problem *(continued)*

Hyland teething tablets cause severe tooth decay and seizures.

Individual Case Safety Report

10631888-01-00-02

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

(b) (6) My son had seizures from these tablets and severe tooth decay on his 4 top teeth

Individual Case Safety Report

10631888-01-00-03

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:--
Medical Conditions: none

Allergies: none

Important Information:

RX Meds:

OTC Meds: Probiotic and children vitamin

Individual Case Safety Report

10631888-01-00-04

Individual Case Safety Report

CaseID: 10638399

Form Approved: OMB No. 0910-0291, Expires: 8/30/2015
See OMB statement on reverse.

10638399-01-00-01

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...rs and manufacturers
...ORY reporting

Mfr Report # 54973 AE # 1579

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13) Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	or	☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
00/00/2012	11/18/2014

5. Describe Event or Problem

SEIZURES REPORTED IN A CHILD.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
- #1 HYLAND'S TEETHING TABLETS
- #2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*
- #1 TEMP RELIEF TEETHING PAIN
- #2

5. Event Abated After Use Stopped or Dose Reduced?
- #1 ☐ Yes ☐ No ☑ Doesn't Apply
- #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?
- #1 ☐ Yes ☐ No ☑ Doesn't Apply
- #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone #	Email Address
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Other Healthcare Profess	☐ Yes ☐ No ☑ Unk.

Individual Case Safety Report

CaseID: 10638399

10638399-01-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ☐☐☐ - ☐☐☐ - ☐☐☐
Device Code ☐☐☐ - ☐☐☐ - ☐☐☐

11. Report Sent to FDA?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name
EDYTA FRACKIEWICZ

Address
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address
STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☑ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☑ Other:
PHARMACY
ASSISTANT

4. Date Received by Manufacturer *(mm/dd/yyyy)*
11/14/2014

5.
(A)NDA # _____
IND # _____
BLA # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973 AE # 1579

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: _____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ☐☐☐ - ☐☐☐ - ☐☐☐
Device Code ☐☐☐ - ☐☐☐ - ☐☐☐
Method ☐☐☐ - ☐☐☐ - ☐☐☐ - ☐☐☐
Results ☐☐☐ - ☐☐☐ - ☐☐☐ - ☐☐☐
Conclusions ☐☐☐ - ☐☐☐ - ☐☐☐ - ☐☐☐

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: _____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS

DEC 03 2014

DEC 04 2014

10638399-01-00-03

Hyland's

CUSTOMER COMPLAINT RECORD

COMPLAINT #: 2589

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 11/14/14

PRODUCT: HYLAND'S TEETHING TABLETS

ITEM CODE: TEET

SIZE: UNKNOWN

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: STORE REPORTS THAT A CHILD'S ATTORNEY REPORTS SEIZURES FOLLOWING USE OF TEETHING TABLETS. SPOKE WITH PHARMACY ON 11/14/14.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 11/14/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1579

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/14/14

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 11-25-14

BY: Eric Bain
QA / QC DIRECTOR

DATE: 11-24-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

DSS

DEC 03 2014

DEC 0

Form # VD1

10638399-01-00-04

NDARD PATHIC USA SINCE 1903

Adverse Event

SAE-0056-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and twenty-seven (127) Adverse Events (AE) which also included thirty-three (33) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

11/21/14
Date

DEC 03 2014

DSS

DEC 04 2014

10638399-01-00-05

10638399

RSE EVENT DATA FORM

AE #: 1579 COMPLAINT #: 2589

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: UNKNOWN CHILD

ADDRESS:

CITY: STATE:

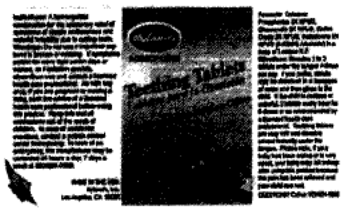
COUNTRY: USA ZIP CODE:

PHONE #:

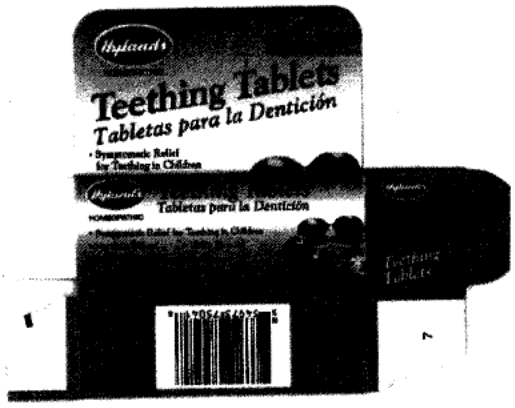
E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: Dyman Dahm DATE: 11-25-14

BY: Eric Bam DATE: 11-24-14
QA / QC DIRECTOR

DSS
DEC 03 2014
DEC 04 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

CDER

CaseID: 10642973

10642973-01-00-01

: Report

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

eporting of problems and rors

FDA USE ONLY
Triage unit sequence # 575111

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	4 Months (b) (6)	☐ Female ☑ Male	70 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/07/2009	12/08/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hyland Teething Tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 07/01/2007 - 08/31/2009	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply
4. Diagnosis or Reason for Use *(Indication)*	8. Event Reappeared After Reintroduction?
#1 Teething	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply
6. Lot # #1 / #2	7. Expiration Date #1 / #2
	9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

DEC - 9 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)* 7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
DEC 09 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

My child took the Hyland Teething Tablets while teething. He was diagnosed with Petit Mal Seizures after taking the tablets.

Individual Case Safety Report

10642973-01-00-02

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

Beginning in August of 2009 we noticed our son blanking out we took him to the doctor and after many test through three different physicians we found he had Petit Mal Seizures.

Individual Case Safety Report

10642973-01-00-03

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:Black/African American
Medical Conditions: Was diagnosed with Petit Mal Seizures

Allergies:

Important Information:

RX Meds:

OTC Meds:

Individual Case Safety Report

10642973-01-00-04

Individual Case Safety Report

CaseID: 10643083

10643083-01-00-01

CDER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 515121

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	7 Months (b) (6)	☐ Female ☑ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☑ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
10/13/2014	12/08/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Name: Hylands Teething tablets
Strength: 2-3 tablets 4 times daily
Manufacturer: A39914

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2-3 tablets 4 times daily	Four times daily	Taken by mouth
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 10/13/2014 - 12/01/2014
#2

4. Diagnosis or Reason for Use (Indication)
#1 Teething Baby
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

CTU
DEC – 9 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

DSS
DEC 09 2014

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

My son began teething at about 7 months and I began to use the product Hylands teething tablets. Soon after me using this product with my son, he had 4 episodes where he would stock breathing and causing im to be very lethargic. He was tehn hospitalized and after 5 days of intensive testing the Dr diagnoised him with seizures because they said that his episodes has characteristics of seizures. He was then given a seizure medication. I truly believe that he began getting these episodes due to the Hylands teething tablets, because before he used this product he was a perfect healthy baby that was never sick.

Individual Case Safety Report

10643083-01-00-02

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

These lab were done between (b) (6) He had an EEG, MRI, EKG, blood work, Gastro testing. None of these labs showed anything that could have caused these events.

Individual Case Safety Report

10643083-01-00-03

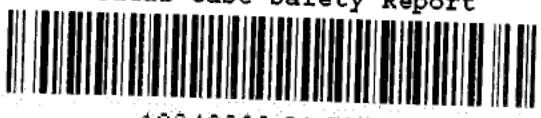
B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:White
Medical Conditions: He was diagnoised with seizures after using this product
---
Allergies:

Important Information:

RX Meds: He is now taking Keppra medication to prevent any other episodes
---
OTC Meds:

Individual Case Safety Report



10643083-01-00-04

Individual Case Safety Report

10648706-01-00-01

by user-facilities,
butors and manufacturers
)ATORY reporting

CaseID: 10648706

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	11 Months	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
11/17/2014	11/25/2014

5. Describe Event or Problem

FATHER REPORTED THAT THE CHILD HAD PRE-EXISTING SYMPTOMS OF A DRY CONSTANT COUGH AND HE PURCHASED THE BABY TEETHING TABLETS BECAUSE HE THOUGHT IT WAS A TEETHING COUGH BECAUSE CHILD SOMETIMES COUGHS WHEN HE IS TEETHING DUE TO EXCESS MUCUS. THE FATHER GAVE 3 TABLETS AND THEN ABOUT 1.5 HOURS LATER THE CHILD'S BREATHING WAS FASTER AND LABORED, HE WAS LETHARGIC AND HIS FEVER WENT UP TO 102 DEGREES. THE WIFE GAVE IBUPROFEN FOR THE SYMPTOMS. A COUPLE OF DAYS LATER THE FEVER CAME BACK. 4 DAYS AFTER GIVING THE HYLAND'S BABY TEETHING TABLETS, AFTER THE INITIAL EPISODE, THE CHILD WAS TAKEN TO THE DOCTOR AND WAS DIAGNOSED WITH RSV (RESPIRATORY SYNCYTIAL VIRUS), A DOUBLE EAR INFECTION AND THRUSH. HE WAS PRESCRIBED AN UNKNOWN ANTIBIOTIC, NYSTATIN AND ORAL STEROIDS. SYMPTOMS ARE IN THE PROCESS OF RESOLVING.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

11/21/14: CHILD TAKEN TO THE DOCTOR AND WAS DIAGNOSED WITH RSV (RESPIRATORY SYNCYTIAL VIRUS), A DOUBLE EAR INFECTION AND THRUSH.

Received
DEC 10 2014

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

DRY CONSTANT COUGH.

CDR

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 3 TABS CRUSHED BY MOUTH	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

IBUPROFEN

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Unique Identifier (UDI) #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

DSS
DEC 11 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

Phone #	Email Address
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☑ No ☐ Unk.

DEC 10 2014

FDA USE ONLY

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 11/17/2014

5. (A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
RAPID & LABORED BREATHING, LETHARGY, FEVER

9. Manufacturer Report Number: 54973 AE # 1582

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360I(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
DEC 11 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

DEC 10 2014

Individual Case Safety Report

10648706-01-00-03

COMPLAINT RECORD

Ca[illegible]48706

COMPLAINT #: 2592

DATE OF COMPLAINT: 11/17/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: THREW AWAY BOTTLE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL ON 11/17/14 – I JUST WANTED TO PASS ALONG THAT MY SON JUST HAD A REACTION TO YOUR TEETHING TABLETS. I AM A FAN OF HYLANDS AND FIGURED MY 11 MONTH BABY COULD BENEFIT FROM THEM. AN HOUR AND A HALF AFTER I GAVE HIM 3 TABLETS, HIS BREATHING BECAME LABORED, HE BECAME LETHARGIC, AND HE SHOT UP TO A 102°F IN A MATTER OF 20 MINUTES. MY WIFE STARTED FREAKING OUT AND THIS WAS THE ONLY THING THAT HE HAD INGESTED. WE GOT HIS FEVER DOWN WITH IBUPROFEN AND HE IMMEDIATELY WENT TO SLEEP. NEEDLESS TO SAY SHE THREW THEM AWAY AND I FEEL THAT YOU NEED TO KNOW ABOUT HIS REACTION. ON 11/24/14 I WAS ABLE TO SPEAK WITH THE CUSTOMER BY PHONE. HE REPORTED THAT THE CHILD HAD SYMPTOMS OF A DRY CONSTANT COUGH – COUGHING EVERY 30 SECONDS. FATHER PURCHASED THE BABY TEETHING TABLETS BECAUSE HE THOUGHT IT WAS A TEETHING COUGH BECAUSE CHILD SOMETIMES COUGHS WHEN HE IS TEETHING DUE TO EXCESS MUCUS. THE FATHER GAVE 3 TABLETS AND THEN ABOUT 1.5 HOURS LATER THE CHILD'S BREATHING WAS FASTER AND LABORED, HE WAS LETHARGIC AND HIS FEVER WENT UP TO 102 DEGREES. THE WIFE GAVE IBUPROFEN AND THIS HELPED THE SYMPTOMS. A COUPLE OF DAYS LATER THE FEVER CAME BACK. 4 DAYS AFTER GIVING THE HYLAND'S BABY TEETHING TABLETS, AFTER THE INITIAL EPISODE, THE CHILD WAS TAKEN TO THE DOCTOR AND WAS DIAGNOSED WITH RSV (RESPIRATORY SYNCYTIAL VIRUS), A DOUBLE EAR INFECTION AND THRUSH. HE WAS PRESCRIBED AN UNKNOWN ANTIBIOTIC, NYSTATIN AND ORAL STEROIDS. THE CHILD IS ON THE "UP AND UP" PER THE FATHER. THE WIFE THREW THE BOTTLE AWAY AND THE CUSTOMER DID NOT REQUEST A REFUND OR REPLACEMENT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/17/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1582

DSS

DEC 11 2014

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/17/14 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 12-01-14

BY: Eric Baum DATE: 12-01-14
QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

DEC 10 2014

FDA/D1

10648706-01-00-04

INDARD
OPATHIC
E USA SINCE 1903

Serious Adverse Event
SAE-0059-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty-one (131) Adverse Events (AE) which also included thirty-six (36) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

11/25/14
Date

DSS
DEC 11 2014
DEC 10 2014

10648706-01-00-05

Case ID: 10648706

Hyland's®

ISE EVENT DATA FORM

AE #: 1582 **COMPLAINT #:** 2592

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

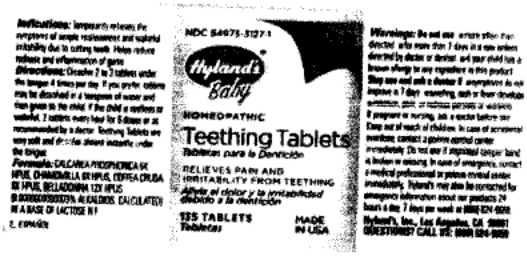
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

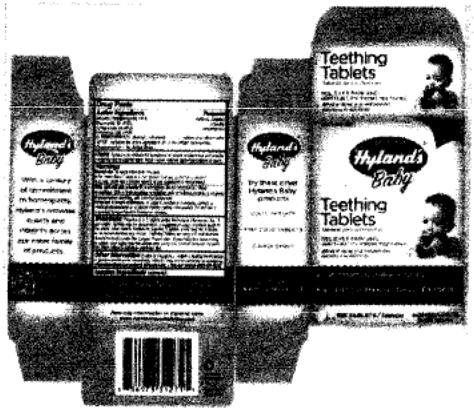
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS
DEC 11 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

DEC 10 2014

REVIEWED BY MANAGEMENT BY: DATE: 12-01-14

BY: DATE: 12-01-14
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

10648708-01-00-01

CaseID: 10648708

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

e by user-facilities,
tributors and manufacturers
DATORY reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	9 Months	☑ Female	____ lbs
In confidence	or ____ Date of Birth:	☐ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
11/15/2014	11/19/2014

5. Describe Event or Problem

THE REPORTER'S 9 MONTH OLD DAUGHTER HAS BEEN USING THE "BABY TEETHING TABLETS" FOR THE PAST 6 MONTHS WITH NO PROBLEMS. THE REPORTER STATED THAT ON 11/13/14 OR 11/14/14, SHE PURCHASED A NEW BOTTLE OF "BABY TEETHING TABLETS" AND BEGAN GIVING HER DAUGHTER DOSES OF THE TABLETS FROM THE NEW BOTTLE ON 11/15/14. PER THE REPORT, ON 11/15/14 AND ON 11/17/14, THE CHILD WOULD "STOP BREATHING, TURN RED, AND START SHAKING", AND THEN WOULD BECOME LETHARGIC. THE REPORTER DESCRIBED THE CHILD AS "GOING IN AND OUT, COHERANT BUT NOT RESPONSIVE". PER THE REPORTER, EACH EPISODE LASTED FOR ABOUT 5 - 7 SECONDS. THE REPORTER STATED THAT THE CHILD WAS GIVEN 1 "TEETHING TABLET" ONCE PER DAY WHEN SYMPTOMS WERE PRESENT; SOMETIMES SHE GAVE 2 OR 3 DOSES OF 1 TABLET PER DAY IF THE CHILD WAS ESPECIALLY "CRANKY". SINCE PURCHASING THIS LAST BOTTLE OF "BABY TEETHING TABLETS", THE REPORTER GAVE HER DAUGHTER 2 TABLETS ON 11/15/14, ONE IN THE MORNING AND ONE IN THE EVENING BEFORE BED, 2 TABLETS ON 11/16/14 IN THE MORNING, AND 1 TABLET ON 11/17/14. THE SHAKING EPISODES OCCURED ABOUT 5 MINUTES AFTER THE DOSES OF "TEETHING TABLETS" WERE GIVEN ON 11/15/14 AND 11/17/14, WITH ONE EPISODE

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

A PHYSICAL EXAM OF THE CHILD WAS NORMAL. PER THE REPORTER, THE DOCTOR COULD NOT GIVE A DIAGNOSIS BECAUSE THEY DID NOT WITNESS THE SYMPTOMS. PER THE REPORTER, NO TESTS WERE ORDERED.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

PER THE REPORTER, THE CHILD HAS NO FAMILY HISTORY OF SEIZURES. PER THE REPORTER, THE CHILD HAS NEVER EXPERIENCED A SIMILAR EVENT/REACTION BEFORE. THE CHILD WAS PRESCRIBED ZANTAC (RANITIDINE) FOR ACID-REFLUX DISEASE, AND SHE HAS TAKEN A DAILY DOSE SINCE THE AGE OF 2 MONTHS. THE CHILD HAS TAKEN TYLENOL AND ANTIBIOTICS IN THE PAST WITH NO ISSUES.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1 TAB BY MOUTH QD-TID	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

DEC 10 2014

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 A09314	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

ZANTAC (RANITIDINE) FOR ACID-REFLUX DISEASE, TYLENOL, AND ANTIBIOTICS

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Unique Identifier (UDI) #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

DSS

DEC 11 2014

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

DEC 10 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

Individual Case Safety Report

CaseID: 10648708

10648708-01-00-02

FDA USE ONLY

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ (Specify)

13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply)
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 11/18/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURE

9. Manufacturer Report Number: 54973 AE # 1580

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death ☐ Serious Injury ☐ Malfunction

2. If Follow-up, What Type?
☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device
☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
DEC 11 2014

DEC 10 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

10648708-01-00-03

NTINUATION PAGE)
se by user-facilities,
tributors, and manufacturers
NDATORY reporting

FORM FDA 3500A (2/13) *(continued)*

Back to Item B.5

B.5. **Describe Event or Problem** *(continued)*

OCCURING ON EACH DAY. THE REPORTER HAS AN APPOINTMENT TO SEE THE DOCTOR REGARDING THESE SYMPTOMS THIS AFTERNOON, 11/18/14.

Back to Item B.6

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

Back to Item B.7

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

Back to Item C.10

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(For continuation of C.10 and/or D.11; please distinguish)*

Back to Item D.11

DSS

DEC 11 2014

Other Remarks

DEC 10 2014

Individual Case Safety Report

10648708-01-00-04

COMPLAINT RECORD

Case # 10648708

COMPLAINT #: 2590

DATE OF COMPLAINT: 11/18/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A09314

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: THE REPORTER'S 9-MONTH OLD DAUGHTER HAS BEEN USING THE "BABY TEETHING TABLETS" FOR THE PAST 6 MONTHS WITH NO PROBLEMS. THE REPORTER STATED THAT ON 11/13/14 OR 11/14/14, SHE PURCHASED A NEW BOTTLE OF "BABY TEETHING TABLETS" AND BEGAN GIVING HER DAUGHTER DOSES OF THE TABLETS FROM THE NEW BOTTLE ON 11/15/14. PER THE REPORTER, ON 11/15/14 AND ON 11/17/14, THE CHILD HAD EPISODES OF WHAT THE REPORTER DESCRIBED AS "THE SHAKES". PER THE REPORTER, ABOUT 5 MINUTES FOLLOWING A DOSE OF THE "TEETHING TABLETS," THE CHILD WOULD "STOP BREATHING, TURN RED, AND START SHAKING," AND THEN WOULD BECOME LETHARGIC. THE REPORTER DESCRIBED THE CHILD AS "GOING IN AND OUT, COHERANT BUT NOT RESPONSIVE." PER THE REPORTER, EACH EPISODE LASTED FOR ABOUT 5 – 7 SECONDS. THE REPORTER STATED THAT THE CHILD WAS GIVEN 1 "TEETHING TABLET" ONCE PER DAY WHEN SYMPTOMS WERE PRESENT; SOMETIMES SHE GAVE 2 OR 3 DOSES OF 1 TABLET PER DAY IF THE CHILD WAS ESPECIALLY "CRANKY". SINCE PURCHASING THIS LAST BOTTLE OF "BABY TEETHING TABLETS", THE REPORTER GAVE HER DAUGHTER 2 TABLETS ON 11/15/14, IN THE MORNING AND ONE IN THE EVENING BEFORE BED, 2 TABLETS ON 11/16/14 IN THE MORNING, AND 1 TABLET ON 11/17/14. THE SHAKING EPISODES OCCURRED ABOUT 5 MINUTES AFTER THE DOSES OF "TEETHING TABLETS" WERE GIVEN ON 11/15/14 AND 11/17/14, WITH ONE EPISODE OCCURING ON EACH DAY. THE REPORTER HAS AN APPOINTMENT TO SEE THE DOCTOR REGARDING THESE SYMPTOMS THIS AFTERNOON, 11/18/14. PER THE REPORTER, THE CHILD HAS NOT BEEN SICK, HAS NOT HAD ANY CONCOMITANT SYMPTOMS SUCH AS A RUNNY NOSE OR AN EARACHE, AND HAS NOT HAD A FEVER TO THE REPORTER'S KNOWLEDGE. PER THE REPORTER, THERE IS NO FAMILY HISTORY OF SEIZURES, AND THE CHILD HAS NEVER HAD AN EPISODE OR REACTION LIKE THIS BEFORE. THE REPORTER STATED THAT THE CHILD TAKES ZANTAC (RANITIDINE) TWICE PER DAY FOR ACID REFLUX; THIS WAS A PRESCRIPTION, AND THE CHILD HAS BEEN TAKING THIS MEDICATION DAILY SINCE THE AGE OF 2 MONTHS. PER THE REPORTER, THE CHILD HAS NO KNOWN ALLERGIES AND HAS TAKEN TYLENOL AND ANTIBIOTICS IN THE PAST WITH NO ISSUES. THE REPORTER STATED THAT SHE UNDERSTANDS THAT THESE EPISODES MAY BE UNRELATED TO THE "TEETHING TABLETS". SHE STATED THAT SHE DOES NOT WISH TO RETURN THE BOTTLE TO THE COMPANY "IN CASE (SHE) NEEDS IT FOR EVIDENCE IN COURT."

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/18/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS DEC 11 2014

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1580

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/18/14

BY: (b) (6)

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 12-01-14

DEC 10 2014

BY: Eric Baum
QA / QC DIRECTOR

DATE: 12-01-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10648708-01-00-05

INDARD
OPATHIC
E USA SINCE 1903

Serious Adverse Event
SAE-0057-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A09314, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A09314 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A09314. The Baby Teething bulk lot # 122448 was tested for total Atropine and Scopolamine and the results were with in specification of ≤ (b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured two other complaints (CC-0382-2014 & CC-0421-2014) has been received for Hyland's Baby Teething Tablets lot # A09314. The complaints were reviewed and the complaints do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A09314.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

11/25/14
Date

DSS
DEC 11 2014

DEC 10 2014

CC-0957-2014
AE-0570-2014

10648708-01-00-06

RSE EVENT DATA FORM

AE #: 1580 **COMPLAINT #:** 2590

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

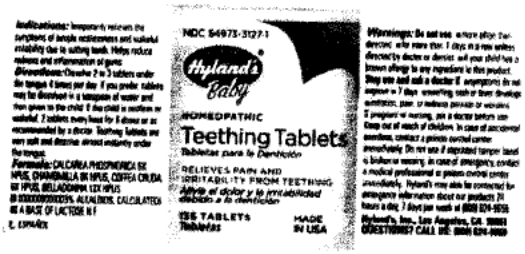
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
DEC 11 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 12-01-14

BY: QA / QC DIRECTOR DATE: 12-01-14

DEC 18 2014

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

10656951-01-00-01

OTC

CaseID: 10656951

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

by user facilities,
outors and manufacturers
for MANDATORY reporting

MEDWATCH

FORM FDA 3500A (2/13)

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event: 18 Months or Date of Birth:
3. Sex: ☑ Female ☐ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: ____ (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 09/00/2014

4. Date of This Report (mm/dd/yyyy): 11/20/2014

5. Describe Event or Problem

MOTHER CALLED ABOUT HER 20 MONTH OLD DAUGHTER WHO HAD A FEBRILE SEIZURE AT 18 MONTHS OLD. SHE WANTED TO KNOW IF HAVING GIVEN HER DAUGHTER BABY TEETHING TABLETS 8 MONTHS PRIOR, COULD BE RELATED TO THE SEIZURE. AT THE TIME OF THE INCIDENT, HER DAUGHTER HAD HAD A FEVER OF 102 FOR 2 - 3 DAYS, OF UNKNOWN CAUSE. THAT MORNING SHE GAVE HER DAUGHTER IBUPROFEN AND 6 HOURS LATER HER DAUGHTER STOOD UP FROM HER BATH AND "PASSED OUT". SHE WAS TAKEN TO THE HOSPITAL WITH A FEVER OF 103.9 AND DIAGNOSED WITH FEBRILE SEIZURE, AND GIVEN IBUPROFEN AND TYLENOL.

Received
DEC 15 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

BLOOD TESTS, CATHETER, AND EARS CHECKED.

DIAGNOSED WITH FEBRILE SEIZURE.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

BORN WITH AN ANUS TOO FAR FORWARD WHICH CAUSES CONSTIPATION. CHILD WAS BORN WITH CHORIOAMNIONITIS AND A HIGH FEVER, TREATED WITH ANTIBIOTICS AT THE MOMENT OF BIRTH. MOTHER ALSO HAD FEVER AT THAT TIME. CHILD HAS SEASONAL ALLERGIES CAN CAUSE EAR INFECTIONS. IT WAS THOUGHT TO BE ROSEOLA, BUT THERE WAS NO RASH.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 1-2TABS, 1-2XDAY PRN
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF OF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 A27113
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-3127-2

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:

Catalog # | Expiration Date (mm/dd/yyyy)

Serial # | Unique Identifier (UDI) #

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
DEC 16 2014

10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)
(b) (6) USA

DEC 15 2014

Phone # (b) (6)

Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☑ Unk.

10656951-01-00-02

FDA USE ONLY

FORM FDA 3500A (2/13) (continued) Page 2 of 5

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:
4. Date Received by Manufacturer (mm/dd/yyyy): 11/20/2014
5. (A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): FEBRILE SEIZURE
9. Manufacturer Report Number: 54973 AE # 1581

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation
3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No (Attach page to explain why not) or provide code: ____
4. Device Manufacture Date (mm/yyyy)
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____
8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
DEC 16 2014
DEC 15 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

CaseID: 10656951

10656951-01-00-03

OMPLAINT RECORD

COMPLAINT #: 2591

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 11/20/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T250

SIZE: 250 TABLETS

LOT NO.: A27113

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: MOTHER CALLED ABOUT HER 20 MONTH OLD DAUGHTER WHO HAD A FEBRILE SEIZURE AT 18 MONTHS OLD. SHE WANTED TO KNOW IF HAVING GIVEN HER DAUGHTER BABY TEETHING TABLETS 8 MONTHS PRIOR, COULD BE RELATED TO THE SEIZURE. AT THE TIME OF THE INCIDENT, HER DAUGHTER HAD HAD A FEVER OF 102°F FOR 2 – 3 DAYS, OF UNKNOWN CAUSE. THAT MORNING SHE GAVE HER DAUGHTER IBUPROFEN AND 6 HOURS LATER HER DAUGHTER STOOD UP FROM HER BATH AND "PASSED OUT". SHE WAS TAKEN TO THE HOSPITAL WITH A FEVER OF 103.9°F AND DIAGNOSED WITH FEBRILE SEIZURE, AND GIVEN IBUPROFEN AND TYLENOL. THE DAUGHTER AND MOTHER HAVE A HISTORY OF HIGH FEVER DURING DAUGHTER'S BIRTH DUE TO CHORIOAMNIONITIS. DAUGHTER WAS TREATED WITH ANTIBIOTICS IMMEDIATELY AFTER BEING BORN. BABY TEETHING TABLETS WERE USED INTERMITTENTLY AS NEEDED FROM 4 – 12 MONTHS OF AGE, DEPENDING ON WHEN SHE WAS 'GNAWING ON HER FINGERS'. DURING THAT TIME THE DAUGHTER NEVER HAD A FEVER OVER 100°F. MOTHER DID USE IBUPROFEN FROM TIME TO TIME.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 11/20/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

DSS

DEC 16 2014

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1581

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/20/14 BY: TUTTI GOULD

DEC 15 2014

SECTION V:

REVIEWED BY MANAGEMENT BY: Rudolf DATE: 12-02-14

BY: Eric Bain DATE: 12-02-14

QA / QC DIRECTOR

cc: QA / QC, Production, Packaging, Shipping / Receiving

Form # VD1

10656951-01-00-04

ANDARD
HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0058-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A27113, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A27113 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A27113. The Baby Teething bulk lot # 118748 was tested for total Atropine and Scopolamine and the results were with in specification of ≤ (b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no related issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # A27113. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A27113.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

12-01-14
Date

DSS
DEC 16 2014

DEC 15 2014

CC-0957-2014
AE-0570-2014

Individual Case Safety Report

10656951-01-00-05

CaseID: 10656951

Hyland's®

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1581 **COMPLAINT #:** 2591

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

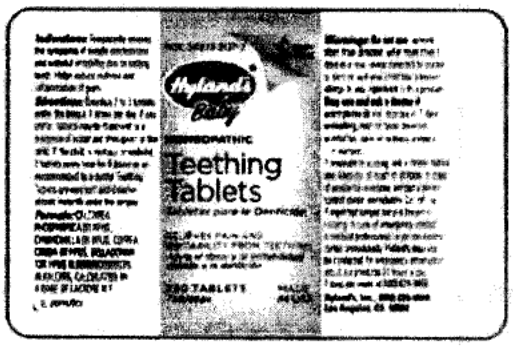
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

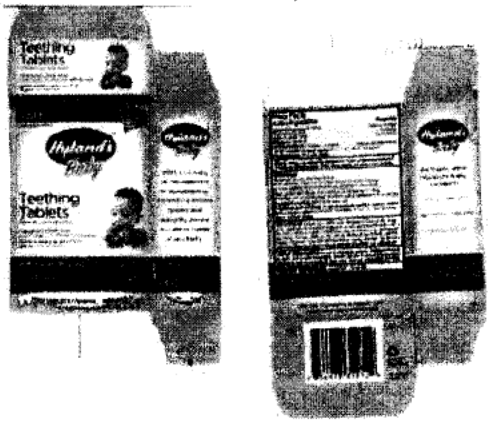
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS

DEC 16 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

DEC 15 2014

REVIEWED BY MANAGEMENT BY: DATE: 12-02-14

BY: QA / QC DIRECTOR DATE: 12-02-14

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 10678285

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statem ent on reverse.

10678285-01-00-01

by user-facilities,
ibutors and manufacturers
DATORY reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

MEDWATCH

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	8 Months	☐ Female	____ lbs
In confidence	or ____ Date of Birth:	☑ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
11/15 - 30/2014	12/08/2014

5. Describe Event or Problem

CHILD VOMITED 15 MINUTES AFTER GETTING BABY TEETHING TABLETS AND THEN AGAIN 5 MINUTES LATER. CHILD WAS "OUT OF IT" AT THIS TIME, SEVERELY LETHARGIC. STARTED VOMITING EVERY FEW MINUTES, DRY HEAVING, NOT RESPONDING. CALLED FOR AN AMBULANCE, CHILD LOST CONSCIOUSNESS 3 TIMES IN THE AMBULANCE. WHITE COUNT WAS ELEVATED AND HE WAS SEVERELY DEHYDRATED. DOCTORS THOUGHT IT COULD HAVE BEEN AN INFECTION. TRANSFERRED TO CHILDREN'S HOSPITAL. DID NOT GET AN ANTIBIOTIC ONLY FLUIDS. THE DOCTORS UNSURE OF DIAGNOSIS. AT A LATER DATE SHE GAVE THE BABY TEETHING TABLETS AGAIN AND THE CHILD STARTED VOMITING. MOTHER GAVE PEDIALYTE. WENT TO THE DOCTOR THE NEXT MORNING. DOCTOR ATTRIBUTED SYMPTOMS TO BELLADONNA IN BABY TEETHING TABLETS BASED ON THE SYMPTOMS. CHILD HAD USED BABY TEETHING TABLETS IN THE PAST WITH NO PROBLEMS.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

RECEIVED
DEC 23 2014
CDR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

TEMPERATURE OF 95.7 - 96.1F RANGE DURING THE FIRST EVENT.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 2TABS HS X 1 DOSE	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 114193	#1	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

DEC 24 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

DEC 23 2014

Phone #	Email Address
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☑ No ☐ Unk.

CaseID: 10678285

10678285-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* — Patient Code ____ - ____ - ____ ; Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 12/01/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): VOMITING, LETHARGY, DEHYDRATION, LOSS CONSCIOUSNESS, ELEVATED WHITE BLOOD CELL COUNT, HOSPITALIZATION
9. Manufacturer Report Number: 54973 AE # 1586

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)* — Patient Code ____ - ____ - ____ ; Device Code ____ - ____ - ____ ; Method ____ - ____ - ____ - ____ ; Results ____ - ____ - ____ - ____ ; Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
DEC 24 2014

DEC 23 2014

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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

10678285-01-00-03

COMPLAINT RECORD

Ca[illegible]678285

COMPLAINT #: 2596

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 12/01/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: 114193

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL ON 12/1/14: I AM DISAPPOINTED IN YOUR TEETHING TABLETS PRODUCT. I PURCHASED YOUR TEETHING TABLETS ON 2 DIFFERENT OCCASIONS, ONE TO HAVE A BOTTLE AT MY PARENT'S HOUSE IF MY CHILDREN NEEDED SOME, AND THEN A BOTTLE TO HAVE AT HOME. I STARTED GIVING MY SON YOUR TEETHING TABLETS WHEN HE WAS APPROXIMATELY 6 MONTHS. I WOULD USUALLY ONLY GIVE IT ONCE MAYBE TWICE A WEEK AND GIVE HIM ONLY 2 TABLETS AT A TIME. I STOPPED GIVING THEM TO HIM AFTER ABOUT 2 WEEKS, AS HE WAS NOT SHOWING SIGNS OF TEETHING, AND DID NOT NEED THEM. AT AROUND 8 MONTHS OLD, (b) (6) (b) (6) I GAVE MY SON 2 TABLETS AS HE WAS FUSSING AND TEETHING. WE ENDED UP IN THE HOSPITAL AS HE BECAME SEVERELY LETHARGIC AND DEHYDRATED FROM VOMITING SO MUCH. I HAD NURSED HIM FOR THE HOUR PRIOR, SO THERE WAS NO POSSIBLE WAY HE WAS DEHYDRATED TO BEGIN WITH, AND HE HAD RECEIVED A BOTTLE THE PRIOR FEEDING. HE HAD NOT HAD ANY NEW MEDICATIONS AND NOTHING NEW IN HIS DIET. WE HAD TO CALL AN AMBULANCE TO TAKE US TO THE HOSPITAL, AND HE LOST CONSCIOUSNESS 3 TIMES ON THE WAY TO THE HOSPITAL. THE DOCTORS AND MYSELF THOUGHT IT MAY JUST BE A VIRUS RUNNING THROUGH HIS SYSTEM AND THAT AFTER HE RECEIVED FLUIDS, HE WOULD BE FINE. WE WERE DISCHARGED FROM THE HOSPITAL THE NEXT MORNING. ABOUT 2 WEEKS LATER, I GAVE HIM 2 MORE TEETHING TABLETS BEFORE BED, AS HE WAS FUSSY AND I HAD FELT SOME TEETH POSSIBLY POKING THROUGH. WE ENDED UP WITH THE SAME RESULT EXCEPT WE DID NOT END UP AT THE HOSPITAL. I TOOK HIM TO THE DOCTOR THE NEXT MORNING TO HAVE HIM CHECKED OUT. THEY WERE ABLE TO MAKE THE DETERMINATION FROM THE SYMPTOMS BOTH TIMES, THAT THE CAUSE WAS THE BELLADONNA IN THE TEETHING TABLETS. HE HAD NEVER SHOWN A PROBLEM PRIOR TO THESE 2 TIMES BEING GIVEN TO HIM, AND NOW ALL OF A SUDDEN THERE BECAME A PROBLEM. I AM WONDERING IF THIS PRODUCT NEEDS TO BE RE-EVALUATED TO ENSURE THERE ISN'T TOO MUCH BELLADONNA IN EACH DOSE FOR INFANTS / TODDLERS. I DO NOT WANT ANOTHER PARENT TO GO THROUGH WHAT WE HAVE HAD TO ENDURE AND POSSIBLY LOSE THEIR CHILD DUE TO THIS REACTION. I SPOKE WITH THE CUSTOMER ON 12/04/14: CHILD VOMITED 15 MINUTES AFTER GETTING TABLETS. VOMITED UP ABOUT 4 – 6 OUNCES. VOMITED 4 OUNCES ABOUT 5 MINUTES LATER. CHILD WAS "OUT OF IT" AT THIS TIME. WAS VOMITING EVERY FEW MINUTES, DRY HEAVING, NOT RESPONDING. THIS HAPPENED AROUND (b) (6) CALLED FOR AN AMBULANCE, CHILD LOST CONSCIOUSNESS 3 TIMES IN THE AMBULANCE. WHITE COUNT WAS ELEVATED AND HE WAS SEVERELY DEHYDRATED. DOCTORS THOUGHT IT COULD HAVE BEEN AN INFECTION. TRANSFERRED TO CHILDREN'S HOSPITAL. DID NOT GET AN ANTIBIOTIC, ONLY FLUIDS. THE DOCTORS WERE NOT SURE WHAT IT COULD HAVE BEEN. COUPLE OF NIGHTS LATER SHE GAVE THE BABY TEETHING TABLETS AND CHILD STARTED VOMITING AGAIN. MOTHER GAVE PEDIALYTE. WENT TO THE DOCTOR THE NEXT MORNING. DOCTOR ATTRIBUTED SYMPTOMS TO BABY TEETHING TABLETS. HE HAS USED BABY TEETHING TABLETS IN THE PAST WITH NO PROBLEMS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/01/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: DEC 2 4 2014

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1586

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 12/01/14 BY: EDYTA FRACKIEWICZ

DEC 2 3 2014

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 12-18-14

BY: Eric Bain
QA / QC DIRECTOR

DATE: 12-12-14

cc: QA / QC Production

10678285-01-00-04

'ANDARD
:OPATHIC
.HE USA SINCE 1903

Serious Adverse Event
SAE-0063-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # 114193, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # 114193 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # 114193. The Baby Teething bulk lot # 114193 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC # 2338) has been received for Hyland's Baby Teething Tablets lot # 114193. The reports were reviewed and they do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # 114193.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

12/10/14
Date

DSS
DEC 2 4 2014

DEC 2 3 2014

CC-0991-2014
AE-0592-2014

10678285-01-00-05

CaseID: 10678285

Hyland's®

ERSE EVENT DATA FORM

AE #: 1586 **COMPLAINT #:** 2596

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

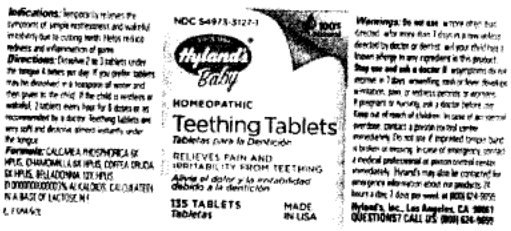
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

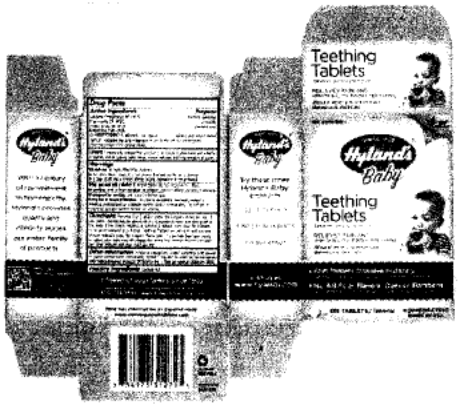
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS

DEC 2 4 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 12-15-14

DEC 2 3 2014

BY: DATE: 12-15-14

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

10678309-01-00-01

CaseID: 10678309

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

user-facilities,
tors and manufacturers
TORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 4 Months — or Date of Birth:
3. Sex: [x] Female [ ] Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- [ ] Death: ____ (mm/dd/yyyy)
- [x] Disability or Permanent Damage
- [x] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [x] Hospitalization - initial or prolonged
- [x] Other Serious (Important Medical Events)
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 08/00/2010

4. Date of This Report (mm/dd/yyyy): 12/03/2014

5. Describe Event or Problem

CHILD HAD A SEIZURE IN (b) (6) 2 WEEKS LATER SHE HAD ANOTHER SEIZURE. DIAGNOSIS: RULE-OUT DEHYDRATION. A WEEK LATER CHILD HAD A STROKE FROM A BRAIN BLEED AND TAKEN TO THE HOSPITAL. BRAIN SCAN SHOWED FLUID BETWEEN BRAIN AND SKULL. (b) (6) WAS INCARCERATED FOR SHAKEN BABY SYNDROME BUT CHILD HAD NO OTHER PHYSICAL SIGNS OF BEING SHAKEN. CHILD ALSO HAD HEMORRHAGING AND HEMATOMA BEHIND THE EYES AND NOW HAS CORTICAL VISUAL IMPAIRMENT.

RECEIVED
DEC 23 2014
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

ALLERGIC TO AMOXICILLIN

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates (If unknown, give duration from/to (or best estimate))
#1
#2

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [x] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [x] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Unique Identifier (UDI) #

5. Operator of Device
- [ ] Health Professional
- [ ] Lay User/Patient
- [ ] Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

DEC 24 2014

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)
(b) (6) USA

DEC 23 2014

Phone #: (b) (6)

Email Address: (b) (6)

2. Health Professional? [ ] Yes [x] No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [x] Unk.

10678309-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 12/01/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURE, BRAIN BLEED, STROKE, SHAKEN BABY SYNDROME, CORTICAL VISUAL IMPAIRMENT
9. Manufacturer Report Number: 54973 AE # 1584

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

DEC 24 2014

DEC 23 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

10678309-01-00-03

COMPLAINT RECORD

Ca[illegible]0678309

COMPLAINT #: 2594

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 12/01/2014

PRODUCT: HYLAND'S TEETHING TABLETS

ITEM CODE: TEET

SIZE: UNKNOWN

LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL ON 12/01/2014: MESSAGE: HELLO, FIRST LET ME START OFF BY SAYING I'M NOT INTERESTED IN COLLECTING ANYTHING OR LAWSUITS. I JUST HAVE A QUESTION. I SAW SOMETHING THAT SAID THE HOMEOPATHIC TEETHING TABLETS WERE RECALLED IN 2010. THAT THEY CAUSED BRAIN BLEEDS AND SEIZURES IN CHILDREN. WAS THIS EVER PROVEN? I'M ASKING BECAUSE MY DAUGHTER SUFFERED FROM BOTH. IN 2010, SHE IS NOW BLIND FROM STROKE AND STILL HAS SEIZURES. BUT SOMEONE WAS INCARCERATED BECAUSE THESE SYMPTOMS SEEMED ALMOST IDENTICAL TO SHAKEN BABY SYNDROME. WAS IT TRUE IS ALL I WANT TO KNOW. I CAN'T LIVE WITH THE POSSIBILITY THAT SOMEONE COULD'VE BEEN FALSELY CONVICTED AND SERVING (b) (6)

SPOKE WITH THE CUSTOMER ON 12/02/2014: CUSTOMER REPORTED CHILD TAKING THE TABLETS IN 2010. INJURY OCCURRED IN (b) (6) WHEN SHE HAD A SEIZURE. 2 WEEKS LATER SHE HAD ANOTHER SEIZURE. RULE OUT DEHYDRATION BY DOCTORS AT THE TIME. A WEEK LATER CHILD HAD A STROKE FROM A BRAIN BLEED – CHILD WAS MOANING AND NERVES WERE GOING OFF. IN THE HOSPITAL THERE WAS A SCAN THAT SHOWED FLUID BETWEEN BRAIN AND SKULL. (b) (6) WAS INCARCERATED FOR SHAKEN BABY SYNDROME FOR (b) (6) BUT CHILD HAD NO OTHER PHYSICAL SIGNS OF BEING SHAKEN. ALSO HAD HEMORRHAGING AND HEMATOMA BEHIND THE EYES AND NOW HAS CORTICAL VISUAL IMPAIRMENT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 12/01/2014

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

DSS

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: DEC 2 4 2014

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1584

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 12/01/14 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 12-12-14 DEC 2 3 2014

BY: Eric Braun
QA / QC DIRECTOR

DATE: 12-12-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10678309-01-00-04

NDARD
PATHIC
USA SINCE 1903

Serious Adverse Event
SAE-0061-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (8) Adverse Events (AE) which also included six (6) Serious Adverse Events (SAE) reported for Hyland's Teething Tablets (TEET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

12/18/14
Date

DSS
DEC 24 2014

DEC 23 2014

10678309-01-00-05

CaseID: 10678309

Hyland's

ERSE EVENT DATA FORM

AE #: 1584 COMPLAINT #: 2594

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

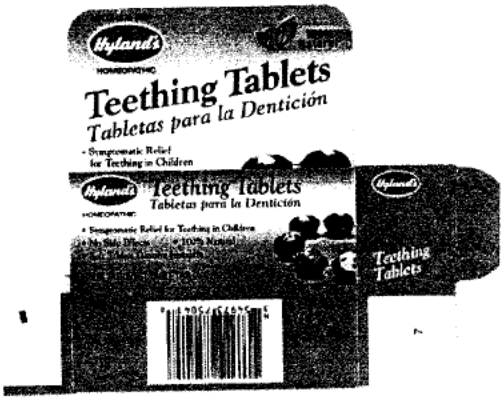
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS

DEC 2 4 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

DEC 2 3 2014

REVIEWED BY MANAGEMENT BY: DATE: 12-12-14

BY: DATE: 12-12-14

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

10678313-01-00-01

CaseID: 10678313

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...by user-facilities, ...utors and manufacturers ...ATORY reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

MEDWATCH

FORM FDA 3500A (2/13)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	2 Years	☑ Female	lbs
In confidence	or Date of Birth:	☐ Male	or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
09/00/2014	12/08/2014

5. Describe Event or Problem

CHILD TOOK 2 TABLETS IN THE EVENING AND THE NEXT MORNING SHE HAD A SEIZURE SHORTLY AFTER WAKING. WENT TO THE HOSPITAL AND STAYED FOR 3 DAYS. EEG AND MRI WERE NORMAL AND PEDIATRIC NEUROLOGIST COULD NOT DETERMINE A CAUSE. ONLY HAD THAT ONE SEIZURE. SYMPTOMS WERE FLOPPING AROUND, EYES ROLLING BACK.

Received

DEC 23 2014

CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

EEG AND MRI WERE NORMAL.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 2 TABLETS PO X 1 DOSE	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 A52214	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: *(mm/dd/yyyy)*

DSS

DEC 24 2014

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

DEC 23 2014

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

PLEASE TYPE OR USE BLACK INK

10678313-01-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address:
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 12/04/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #:

7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURE

9. Manufacturer Report Number: 54973 AE # 1585

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
DEC 24 2014

DEC 23 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

10678313-01-00-03

COMPLAINT RECORD

Hyland's

Co[illegible]678313

COMPLAINT #: 2595

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 12/04/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A52214

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: 3 MONTHS AGO CHILD TOOK 2 TABLETS FOR THE FIRST TIME EVER IN THE EVENING AND THE NEXT MORNING SHE HAD A SEIZURE SHORTLY AFTER WAKING. WENT TO THE HOSPITAL AND STAYED 3 DAYS. EEG AND MRI WERE NORMAL AND PEDIATRIC NEUROLOGIST COULD NOT DETERMINE A CAUSE. ONLY HAD THAT ONE SEIZURE. SYMPTOMS WERE FLOPPING AROUND, EYES ROLLING BACK. WANTS A REFUND – SEND SRP. IS CONSIDEREING SEEING A LAWYER. WANTS TO KNOW WHY FACEBOOK INFORMATION SAYS THAT BABY TEETHING TABELTS CAUSES SEIZURES. CUSTOMER ALSO SENT THE FOLLOWING E-MAIL ON 12/04/14 TO MARY BORNEMAN: THIS IS JUST TO INFORM YOU THAT MY DAUGHTER HAD A SEIZURE ON YOUR TEETHING TABELTS AND I THINK YOU NEED TO PUT A RECALL ON YOUR TABLETS AND I AM GOING TO CONSULT A LAWYER.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/04/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

DSS

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: DEC 24 2014

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1585

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 12/04/14

BY: EDYTA FRACKIEWICZ

DEC 23 2014

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 12-15-14

EJB 12-12-14

BY: Eric Bunn
QA / QC DIRECTOR

DATE: ~~12-12-14~~ 12-12-14

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

10678313-01-00-04

Serious Adverse Event
SAE-0062-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A52214, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A52214 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A52214. The Baby Teething bulk lot # 123494 was tested for total Atropine and Scopolamine and the results were with in specification of ≤ (b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # A52214. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A52214.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

12/10/14
Date

DSS

DEC 24 2014

DEC 23 2014

CC-0990-2014
AE-0591-2014

Individual Case Safety Report

10678313-01-00-05

CaseID: 10678313

Hyland's

...RSE EVENT DATA FORM

AE #: 1585 **COMPLAINT #:** 2595

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

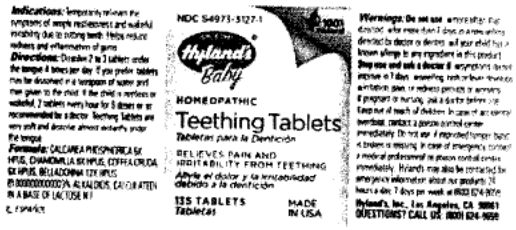
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

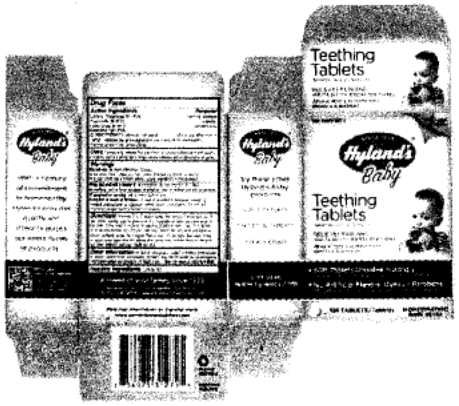
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS

DEC 2 4 2014

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

DEC 2 3 2014

REVIEWED BY MANAGEMENT BY: DATE: 12-16-14

BY: QA / QC DIRECTOR DATE: 12-15-14

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

10684780-01-00-01

CaseID: 10684780

...mer Report

...Y reporting of
...uct problems and
...product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

1/3

FDA USE ONLY
Triage unit sequence # 577223

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	11 Months (b) (6)	☐ Female ☑ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
12/29/2014	12/29/2014

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4/3 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hyland Teething Tablets
Strength: Hyland Teething Tablets
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	Taken by mouth
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 09/01/2014 - 12/29/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name
CTU

3. Manufacturer Name, City and State
DEC 30 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)* 7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: (b) (6)
Address:

DSS
DEC 30 2014

City: State: -- ZIP:

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

I've been giving my son Hyland Teething Tablets for the past few days and his cheeks have turned bright red and slightly swollen.

Individual Case Safety Report

10684780-01-00-02

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:White
Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds:

Individual Case Safety Report

10684780-01-00-03

Individual Case Safety Report

10691018-01-00-01

CaseID: 10691018

OTC

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

ser-facilities,
rs and manufacturers
ORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 9 Months — or Date of Birth:
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 10/00/2014

4. Date of This Report *(mm/dd/yyyy)*: 12/10/2014

5. Describe Event or Problem

SON WAS HAVING SEIZURES IN (b) (6) WHILE TAKING BABY TEETHING TABLETS. ON THE DAY OF THE SEIZURE CHILD TOOK 1 TABLET IN THE MORNING. MOTHER PUT CHILD IN THE SWING AND THEN SHE FOUND HIM STIFF, ARMS WERE OUT, EYES ROLLED IN THE BACK OF THE HEAD, NOT RESPONDING TO MOTHER, SHAKING X 30 SECONDS. WHEN THE SEIZURE STOPPED THE CHILD VOMITED AND STARTED CRYING. TOOK HIM TO THE BATHROOM TO CLEAN HIM OFF AND HE HAD ANOTHER SEIZURE THAT LASTED 15 MINS. WENT TO THE HOSPITAL. IN THE HOSPITAL DID BLOODWORK (NORMAL) AND CHILD HAS AN MRI AND EEG SCHEDULED FOR NEXT MONTH. SPECIALIST SAID THE CHILD LOOKS NORMAL.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

MRI AND EEG SCHEDULED FOR NEXT MONTH.

Received

DEC 3 1 2014

CDR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

FAMILY HISTORY OF AUTISM ON THE FATHER'S SIDE.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
- #1 HYLAND'S BABY TEETHING TABLETS
- #2

2. Dose, Frequency & Route Used
- #1 1TAB RUBBD ON GUMSX8HRS
- #2

3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
- #1
- #2

4. Diagnosis for Use *(Indication)*
- #1 TEMP RELIEF OF TEETHING PAIN
- #2

5. Event Abated After Use Stopped or Dose Reduced?
- #1 ☐ Yes ☐ No ☑ Doesn't Apply
- #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
- #1
- #2

7. Exp. Date
- #1
- #2

8. Event Reappeared After Reintroduction?
- #1 ☐ Yes ☐ No ☑ Doesn't Apply
- #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Unique Identifier (UDI) #

5. Operator of Device
- ☐ Health Professional
- ☐ Lay User/Patient
- ☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

JAN 0 5 2015

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

JAN 0 2 2015

Phone # (b) (6)

Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☑ Unk.

Individual Case Safety Report

CaseID: 10691018

10691018-01-00-02

f 5

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   Name: EDYTA FRACKIEWICZ
   Address: HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061
   Email Address: STANDARD@HYLANDS.COM
2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 12/08/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #:
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURES, VOMITING
9. Manufacturer Report Number: 54973 AE # 1587

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JAN 05 2015

JAN 02 2015

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

JAN 02 2015

Individual Case Safety Report

10691018-01-00-03

...AINT RECORD

Ca...10691018

COMPLAINT #: 2597

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 12/08/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: CAN'T FIND BOTTLE

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SON WAS HAVING SEIZURES IN (b) (6) WHILE TAKING BABY TEETHING TABLETS. MOTHER GIVING 1 TABLET AND RUBBING IT ON CHILD'S GUMS EVERY 8 HOURS 3X / WEEK FOR ONE MONTH. ON THE DAY OF THE SEIZURE CHILD TOOK 1 TABLET IN THE MORNING. THEN CHILD ATE SOME OATMEAL AND WENT INTO THE SWING. MOTHER SAW CHILD IN THE SWING, STIFF, ARMS WERE OUT, EYES ROLLED IN THE BACK OF THE HEAD, NOT RESPONDING TO MOTHER, SHAKING X 30 SECONDS. WHEN THE SEIZURE STOPPED THE CHILD VOMITED AND STARTED CRYING. TOOK HIM TO THE BATHROOM TO CLEAN HIM OFF AND HE HAD ANOTHER SEIZURE THAT LASTED 15 SECONDS. WENT TO THE HOSPITAL. IN THE HOSPITAL HAD BLOODWORK (NORMAL) AND CHILD HAS AN MRI AND EEG SCHEDULED FOR NEXT MONTH. SPECIALIST SAID THE CHILD LOOKS NORMAL. NO FAMILY HISTORY OF SEIZURES. FAMILY HISTORY OF AUTISM ON THE FATHER'S SIDE. OFFERED A REFUND AND SHE ACCEPTED – PAID AROUND $ 5.00. CALLED MOTHER ON 12/09/14 TO ASK HER IF SHE FOUND THE BOTTLE BECAUSE I WANTED THE LOT #. SHE SAID THAT SHE RECENTLY MOVED AND CAN'T FIND THE BOTTLE AND IT MAY BE SOMEWHERE IN THE GARAGE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/08/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

JAN 05 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1587

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 12/08/14 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 12-19-14

BY: QA / QC DIRECTOR DATE: 12-19-14

JAN 02 2015

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

STANDARD HOMEOPATHIC
A SINCE 1903

Serious Adverse Event
SAE-0065-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty (130) Adverse Events (AE) which also included forty (40) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

12/17/14
Date

DSS
JAN 05 2015

JAN 02 2015

Individual Case Safety Report

10691018-01-00-05

CaseID: 10691018

Hyland's

EVENT DATA FORM

AE #: 1587 COMPLAINT #: _____

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6) STATE: (b) (6)

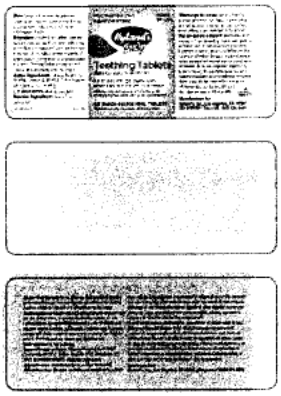
COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL: _____

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

DSS

JAN 05 2015

CORRECTIVE ACTION(S) COMPLETED BY: _____ DATE: _____

JAN 02 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Wall DATE: 12-19-14

BY: Eric Bau DATE: 12-19-14

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

10723317-01-00-01

CaseID: 10723317

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...y user-facilities,
...utors and manufacturers
...ATORY reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

FORM FDA 3500A (2/13)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	9 Months or Date of Birth:	☑ Female ☐ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - ☑ Death: (b) (6) *(mm/dd/yyyy)*
   - ☐ Disability or Permanent Damage
   - ☐ Life-threatening
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Hospitalization - initial or prolonged
   - ☐ Other Serious (Important Medical Events)
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
07/09/2014	12/30/2014

5. Describe Event or Problem

(b) (6) CHILD PASSED AWAY AT THE AGE OF 9 MONTHS. WAS CHILD'S FIRST TIME USING THE BABY TEETHING TABLETS. MOTHER GAVE 2 TABLETS CRUSHED IN CHILD'S MOUTH. PUT CHILD TO BED AND THEN SHE GOT A BOTTLE, WHEN SHE FINISHED THE BOTTLE THEN THE BOTTLE WAS TAKEN AWAY BY THE MOTHER AND THE MOTHER LEFT HER. 45 MINUTES LATER MOTHER CHECKED ON HER AND SHE WAS DEAD IN THE CRIB. CHILD WAS FOUND WITH A PUDDLE OF VOMIT NEXT TO HER AT THE TIME OF DEATH. CAUSE OF DEATH UNKNOWN. ON THE DAY THIS HAPPENED CHILD WAS "FUSSING REALLY BAD" AND MOTHER FELT A TOOTH COMING IN ON THE BOTTOM.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD BORN 5 WEEKS PREMATURE

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
   - #1 HYLAND'S BABY TEETHING TABLETS
   - #2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 2 TABS CRUSHED IN MOUTH	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

RECEIVED

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1 JAN 14 2015	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-3 CDR

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
    ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

JAN 15 2015

Phone #	Email Address
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA JAN 14 2015	☐ Yes ☐ No ☑ Unk.

PLEASE TYPE OR USE BLACK INK

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name
EDYTA FRACKIEWICZ

Address
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

Email Address
STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
12/30/2014

5. (A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
DEATH

9. Manufacturer Report Number
54973 AE # 1591

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

JAN 15 2015

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

JAN 14 2015

10723317-01-00-03

MPLAINT RECORD

C... 723317

COMPLAINT #: 2601

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 12/26/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABLETS

LOT NO.: THREW AWAY BOTTLE

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL MESSAGE: I GAVE MY DAUGHTER THE HYLANDS TEETHING TABLETS AN SHE PASSED AWAY THAT NIGHT I DNT THINK THAT MEDICINE SHOULD BE ON THE SHELFS. E. FRACKIEWICZ CALLED THE CUSTOMER ON 12/30/2014 TO OBTAIN MORE INFORMATION. (b) (6) CHILD PASSED AWAY AT THE AGE OF 9 MONTHS. WAS HER FIRST TIME USING THE BABY TEETHING TABLETS. GAVE 2 TABLETS CRUSHED IN CHILD'S MOUTH. PUT CHILD TO BED AND THEN SHE GOT A BOTTLE, WHEN SHE FINISHED THE BOTTLE THEN THE BOTTLE WAS TAKEN AWAY BY THE MOTHER AND THE MOTHER LEFT HER. 45 MINUTES LATER MOTHER CHECKED ON HER AND SHE WAS DEAD IN THE CRIB. DOCTOR RUNNING ALL KINDS OF TESTS FOR CAUSE OF DEATH. MOTHER THINKS BABY TEETHING TABLETS CAUSED HER TO HAVE A SEIZURE AND DIE. MOTHER DID NOT CONTACT HYLAND'S SOONER BUT SHE HAS BEEN DOING RESEARCH ON THE INTERNET ABOUT BABY TEETHING TABLETS AND READING THAT BELLADONNA IS CAUSING SEIZURES IN BABIES. SHERIFF IS LOOKING THROUGH MEDICAL FILES AND LOOKING INTO THE BABY TEETHING TABLETS TO DETERMINE A CAUSE OF DEATH. CHILD WAS FOUND WITH A PUDDLE OF VOMIT NEXT TO HER AT THE TIME OF DEATH. SHERIFF, DETECTIVE, AMBULANCE CAME OUT AND TRIED TO RESUCITATE HER FOR AN HOUR BUT WERE UNSUCCESSFUL. MOTHER DOES NOT HAVE A CAUSE OF DEATH OR DEATH CERTIFICATE. ON THE DAY THIS HAPPENED CHILD WAS "FUSSING REALLY BAD" AND MOTHER FELT A TOOTH COMING IN ON THE BOTTOM. CHILD WAS 5 WEEKS PREMATTURE BUT NO OTHER HEALTH ISSUES. NO NEW FOODS ON THAT DAY, JUST RECEIVED A BOTTLE OF MILK. CUSTOMER DID NOT REQUEST A REFUND OR REPLACEMENT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/26/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1591

DSS

JAN 15 2015

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 12/26/2014

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: EDW 01-02-15 ~~01-02-14~~

BY: QA / QC DIRECTOR

DATE: 01-02-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

JAN 14 2015

Form # VD1

10723317-01-00-04

NDARD PATHIC
JSA SINCE 1903

Serious Adverse Event
SAE-0069-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that since the reported occurrence of the incident in July 2014 that there have been a total of two hundred sixty seven (267) complaints received, of those one hundred sixty-six (166) were further classified as Adverse Events (AE) and of those forty-six (46) Serious Adverse Events (SAE) have been reported for Hyland's Baby Teething Tablets (BTET). None of those other reports indicated any "death" related to the use of our products. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

12/31/14
Date

DSS
JAN 15 2015

JAN 14 2015

10723317-01-00-05

CaseID: 10723317

Hyland's®

SE EVENT DATA FORM

AE #: 1591 **COMPLAINT #:** 2601

SECTION I: **PATIENT INFORMATION** *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

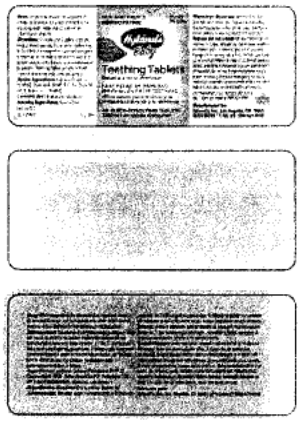
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS

JAN 15 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 01-02-15

BY: Eric Braun DATE: 01-02-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JAN 14 2015

10792549-01-00-01

OTC

CaseID: 10792549

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...y user-facilities,
...utors and manufacturers
...ATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13) Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	5 Months	☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
01/16/2015	01/28/2015

5. Describe Event or Problem

CHILD HAD ASPHYXIA AT BIRTH AND WAS DELIVERED VIA EMERGENCY C-SECTION RESULTING IN BLEEDING ON THE BRAIN WHICH PREDISPOSES HIM TO SEIZURES. CHILD HAD A SEIZURE ON (b) (6) AND HE WAS REALLY TIRED PRIOR TO THIS TIME. HE STARTED HAVING 3 - 4 SEIZURES PER DAY. TREATED WITH KEPPRA AND TOPAMAX. CT SCAN WAS NORMAL. EEG WAS ABNORMAL (UNKNOWN RESULTS). CURRENTLY HAVING 1 - 2 SEIZURES PER DAY EVEN WHILE ON ANTI-SEIZURE MEDICATION.

Received
FEB 11 2015
COR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

EEG WAS ABNORMAL (UNKNOWN RESULTS). CT SCAN WAS NORMAL.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD HAD ASPHYXIA AT BIRTH AND WAS DELIVERED VIA EMERGENCY C-SECTION RESULTING IN BLEEDING ON THE BRAIN WHICH PREDISPOSES HIM TO SEIZURES.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 2TABSINFORMULAX1MONTH	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF OF TEETHING SX	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A63714	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

KEPPRA, TOPAMAX, AND TYLENOL.

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

DSS
FEB 12 2015

Phone #	Email Address
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☑ No ☐ Unk.

FEB 11 2015

10792549-01-00-02

FDA USE ONLY

1. Check One	2. UF/Importer Report Number
☐ User Facility ☐ Importer	

3. User Facility or Importer Name/Address

4. Contact Person	5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)	7. Type of Report	8. Date of This Report (mm/dd/yyyy)
	☐ Initial ☐ Follow-up # ____	

9. Approximate Age of Device	10. Event Problem Codes (Refer to coding manual)
	Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____

11. Report Sent to FDA?	12. Location Where Event Occurred
☐ Yes ____ (mm/dd/yyyy) ☐ No	☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No	

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)	2. Phone Number
Name: EDYTA FRACKIEWICZ	310-768-0700
Address: HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061	3. Report Source (Check all that apply): ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
Email Address: STANDARD@HYLANDS.COM	

4. Date Received by Manufacturer (mm/dd/yyyy)	5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
01/22/2015	
6. If IND, Give Protocol #	
7. Type of Report (Check all that apply): ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____	
9. Manufacturer Report Number: 54973 AE # 1596	8. Adverse Event Term(s): ATONIC SEIZURES, LETHARGY

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event	2. If Follow-up, What Type?
☐ Death ☐ Serious Injury ☐ Malfunction	☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____	4. Device Manufacture Date (mm/yyyy) 5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes (Refer to coding manual)

Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type	8. Usage of Device
☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____	☐ Initial Use of Device ☐ Reuse ☐ Unknown
	9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
FEB 12 2015

FEB 11 2015

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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

PLAINT RECORD

Case 2549

10792549-01-00-03

COMPLAINT #: 2606

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 01/22/15

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T250

SIZE: 250 TABLETS

LOT NO.: A63714

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SPOKE WITH CUSTOMER ON 01/27/2015. CHILD WAS BORN WITH BLEEDING ON THE BRAIN WHICH PREDISPOSES HIM TO SEIZURES. HAD ASPHYXIA AT BIRTH WITH EMERGENCY C-SECTION. MOTHER WONDERING IF HYLAND'S TEETHING TABLETS COULD HAVE CAUSED CHILD'S ATONIC SEIZURES. WAS GIVING THE TEETHING TABLETS 2 TABS IN THE CHILD'S FORMULA EVERY OTHER FEEDING X 1 MONTH. CHILD HAD A SEIZURE ON (b) (6) AND HE WAS REALLY TIRED PRIOR TO THIS TIME. LAST DOSE OF BABY TEETHING TABLETS WAS ON 01/15/15. STARTED HAVING 3 – 4 SEIZURES PER DAY. TOOK HIM TO THE ER AND THEN HE WAS TAKEN TO (b) (6) AND HE WAS HOSPITALIZED THERE AND WAS GIVEN AN EEG AND CT SCAN. CT SCAN WAS NORMAL. EEG WAS ABNORMAL (MOTHER DOES NOT KNOW THE RESULTS). CURRENTLY HAVING 1 – 2 SEIZURES PER DAY EVEN WHILE ON ANTI-SEIZURE MEDICATION. HAS NOT GIVEN BABY TEETHING TABLETS SINCE 01/15/15 AND GIVES TYLENOL FOR TEETHING PAIN. WOULD LIKE A REFUND. PAID $ 9.98. CUSTOMER SENT THE FOLLOWING E-MAIL MESSAGE: DEAR SIR OR MADAM: I AM WRITING AS A CONCERNED PARENT OF A 5MO OLD BOY WHO HAS BEEN TEETHING FOR A COUPLE OF MONTHS NOW..I INQUIRED FROM SEVERAL PEOPLE ON TEETHING TABLETS AND THEY HAVE WORKED GREAT BUT HERE RECENTLY WITHIN THE LAST 2 WEEKS MY SON HAS BECOME SUPER SLEEPY AND LETHARGIC...WELL THEN CAME SEIZURES AND HE HAD SEIZURES 3 – 4 TIMES A DAY...I WILL NO LONGER USE THIS PRODUCT ON MY CHILD EVEN THOUGH I AM NOT 100% SURE IF THE TEETHING TABLETS ARE THE PROBLEM...MY SON SPENT 3 DAYS IN THE PEDIATRIC NEURO THIS PAST WEEKEND...PLEASE RETEST YOUR PRODUCT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 01/22/15

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE: DSS

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1596 FEB 12 2015

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 01/22/15 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 02-02-15

BY: QA / QC DIRECTOR DATE: 02-02-15

FEB 11 2015

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

10792549-01-00-04

NDARD PATHIC USA SINCE 1903

Serious Adverse Event
SAE-0005-2015

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A63714, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A63714 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A63714. The Baby Teething bulk lot # 118748 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

A review of the Customer Complaint system found one other complaint (CC-0896-2014) related to this lot. The complaints were reviewed and they do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A63714.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

~~01-29-15~~ 01-29-15

Date

was 01-30-15 (EE)

DSS

FEB 12 2015

CC-0079-2015
AE-0044-2015

FEB 11 2015

10792549-01-00-05

10792549

SE EVENT DATA FORM

AE #: 1596 **COMPLAINT #:** 2606

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

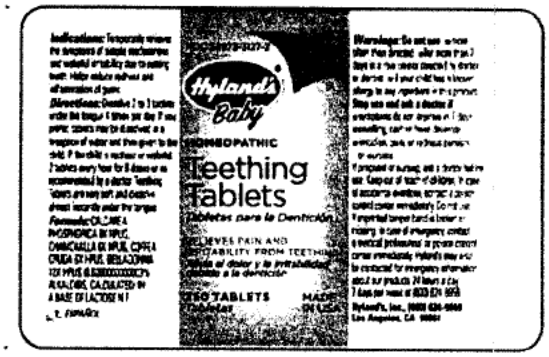
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

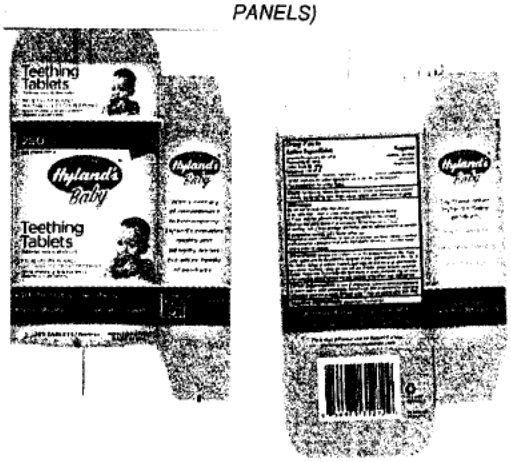
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE: DSS FEB 12 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 02-03-15

BY: QA / QC DIRECTOR DATE: 02-02-15

FEB 11 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 10855443

10855443-01-00-01

sumer Report

RY reporting of duct problems and product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

The FDA Safety Information and Adverse Event Reporting Program

CTU

1 of 5

FDA USE ONLY
Triage unit sequence #
583620

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	4.5 Months (b) (6)	☐ Female ☑ Male	14.5 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
02/15/2015	02/15/2015

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: teething tablets
Strength: hylands teething tablets
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2-3 tablets 4x/ day	Four times daily	Taken by mouth
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 02/07/2015 - 02/14/2015
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething in infant
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 b21114	#1	54973-3127-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

FEB 18 2015

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
FEB 18 2015

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

Severe constipation in infant Severe agitation

Individual Case Safety Report

10855443-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:White
Medical Conditions: N/a

Allergies: Nka

Important Information:

RX Meds: Zantac

OTC Meds: Infant Tylenol, polysivol

Individual Case Safety Report

10855443-01-00-03

CaseID: 10862441

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

10862441-01-00-01

...ser-facilities, ...rs and manufacturers ...ORY reporting

OTC

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence

2. Age at Time of Event: 7 Months or Date of Birth:

3. Sex: ☐ Female ☑ Male

4. Weight: 24 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 01/27/2015

4. Date of This Report *(mm/dd/yyyy)*: 01/29/2015

5. Describe Event or Problem

CHILD CARE CENTER REPORTS CHILD EXPERIENCED SEIZURES THIS PAST WEEKEND WHILE TAKING TEETHING TABLETS. ACCORDING TO THE REPORTER, THE MOTHER STATED THE CHILD'S SEIZURES STOPPED AFTER THE MOTHER DISCONTINUED ADMINISTERING THE TEETHING TABLETS.

FOLLOW-UP CONVERSATION WITH THE CHILD'S MOTHER ON 01/28/15: MOTHER STATES THE CHILD HAS BEEN TEETHING FOR SEVERAL MONTHS. SINCE THE TEETHING SYMPTOMS WERE MILD, SHE DID NOT OFFER THE CHILD ANY MEDICATION. HOWEVER, OVER THE PAST FEW WEEKS THE CHILD SEEMS TO HAVE BECOME MORE IRRITABLE, FUSSY AND TROUBLED BY THE TEETHING PROCESS -- PARTICULARLY IN THE LATE AFTERNOON AND EARLY EVENING. SO HAVING USED THE TEETHING TABLETS WITH HER OLDER CHILD WITH GOOD RESULTS, SHE WENT TO WALMART AND "PICKED UP A BOTTLE OF TEETHING TABLETS". APPROXIMATELY TWO WEEKS AGO, SHE ADMINISTERED 2 TEETHING TABLETS TO THE CHILD EVERY DAY IN THE LATE AFTERNOON / EVENING WHEN THE CHILD BECAME FUSSY. WITHIN ONE HOUR OF THE DOSE SHE OBSERVED THE CHILD EXPERIENCING SYMPTOMS OF "TWITCHING, MOVING HIS HEAD FAST FROM SIDE TO SIDE, MOVING HIS HEAD BACKWARDS, AND HIS EYES WENT UP". THE CHILD CARE STAFF

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Received FEB 19 2015 CDR

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

FAMILY HISTORY OF ANAPHYLAXIS TO IBUPROFEN

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used

#1 2 TABS DAILY BY MOUTH

#2

3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*

#1

#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING SYMPTOMS

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1 A22214

#2

7. Exp. Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-3

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date *(mm/dd/yyyy)*

Serial #

Unique Identifier (UDI) #

5. Operator of Device

- ☐ Health Professional
- ☐ Lay User/Patient
- ☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

FEB 19 2015

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (b) USA (b) (6)

DSS FEB 20 2015

Phone # (b) (6)

Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☑ Unk.

10862441-01-00-02

FDA USE ONLY

1. Check One: ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report: ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home ☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 01/27/2015

5. (A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURES

9. Manufacturer Report Number: 54973 AE # 1595

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
FEB 20 2015

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

FEB 19 2015

10862441-01-00-03

INUATION PAGE)
by user-facilities,
utors, and manufacturers
)ATORY reporting

FORM FDA 3500A (2/13) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

INITIALLY NOTICED THE SYMPTOMS AND REPORTED THE SYMPTOMS TO THE MOTHER. THE CHILD CARE STAFF ATTRIBUTED THE SYMPTOMS TO THE CHILD BEING BOTHERED BY THE TAG IN HIS CLOTHES. HOWEVER, SUBSEQUENT TO THE CONVERSATION WITH THE CHILD CARE STAFF, THE MOTHER NOTICED THE SAME SYMPTOMS AFTER ADMINISTERING TWO TEETHING TABLETS. ON 01/24/15, THE CHILD'S MOTHER DISCONTINUED ADMINISTERING THE TEETHING TABLETS AND REPORTS THE CHILD HAS NOT EXPERIENCED ANY OF THE SYMPTOMS DESCRIBED ABOVE SINCE.

THE CHILD HAS AN APPOINTMENT WITH HIS HEALTHCARE PRACTITIONER ON 2/2/15.

Back to Item B.5

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

Back to Item B.6

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Back to Item B.7

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Back to Item C.10

Other Remarks

Back to Item D.11

OMPLAINT RECORD

CaseID: 10862441

10862441-01-00-04

COMPLAINT #: 2605

DATE OF COMPLAINT: 01/27/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A22214

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: A REPRESENTATIVE OF A CHILD CARE CENTER CALLED TO INQUIRE ABOUT THE STATUS OF OUR TEETHING TABLETS AND OBTAIN INFORMATION ABOUT BELLADONNA CONTAINED IN THE PRODUCT. THE REPORTER WAS INFORMED BY THE MOTHER OF ONE OF THE CHILDREN ATTENDING THE CENTER THAT HER CHILD EXPERIENCED SEIZURES THIS WEEKEND WHILE TAKING THE TEETHING TABLETS. I PROVIDED OUR SAFETY INFORMAITON AND REFERRED HER TO HYLANDSTEETHING.COM FOR ADDITIONAL INFORMATION. FOLLOW UP CONVERSATION WITH THE CHILD'S MOTHER ON 1/28/15: MOTHER STATES THE CHILD HAS BEEN TEETHING FOR SEVERAL MONTHS. SINCE THE TEETHING SYMPTOMS WERE MILD, SHE DID NOT OFFER THE CHILD ANY MEDICATION. HOWEVER, OVER THE PAST FEW WEEKS THE CHILD SEEMS TO HAVE BECOMRE MORE IRRITABLE, FUSSY AND TROUBLED BY THE TEETHING PROCESS – PARTICULARLY IN THE LATE AFTERNOON AND EARLY EVENING. SO HAVING USED THE TEETHING TABLETS WITH HER OLDER CHILD WITH GOOD RESULTS, SHE WENT TO WALMART AND "PICKED UP A BOTTLE OF TEETHING TABLETS". APPROXIMATELY TWO WEEKS AGO, SHE ADMINISTERED 2 TEETHING TABLETS TO THE CHILD EVERY DAY IN THE LATE AFTERNOON / EVENING WHEN THE CHILD BECAME FUSSY. WITHIN ONE HOUR OF THE DOSE SHE OBSERVED THE CHILD EXPERIENCING SYMPTOMS OF "TWITCHING, MOVING HIS HEAD FAST FROM SIDE TO SIDE, MOVING HIS HEAD BACKWARDS, AND HIS EYES WENT UP". ACCORDING TO THE MOTHER, THE CHILD CARE STAFF INITIALLY NOTICED THE SYMPTOMS AND REPORTED THE SYMPTOMS TO HER. THE CHILD CARE STAFF ATTRIBUTED THE SYMPTOMS TO THE CHILD BEING BOTHERED BY THE TAG IN HIS CLOTHES. HOWEVER, SUBSEQUENT TO THE CONVERSATION WITH THE CHILD CARE STAFF, THE MOTHER NOTICED THE SAME SYMPTOMS AFTER ADMINISTERING TWO TEETHING TABLETS. ON 01/24/15, THE CHILD'S MOTHER DISCONTINUED ADMINISTERING THE TEETHING TABLETS AND REPORTS THE CHILD HAS NOT EXPERIENCED ANY OF THE SYMPTOMS DESCRIBED ABOVE SINCE. THE MOTHER STATES SHE BELIEVES THE SYMPTOMS ARE ATTRIBUTED TO THE TEETHING TABLETS SINCE SHE LEARNED THERE WERE "SEIZURES CAUSED BY THE OLD FORMULA." MOTHER REQUESTS REFUND.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 01/27/15

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CATHERINE DOW

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1595

ADVERSE EVENT SERIOUS: (Y) / N

FEB 19 2015 DSS

ADVERSE EVENT REPORTED ON: 01/27/15 BY: CATHERINE DOW

FEB 20 2015

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 02-09-15

BY: Eric Bacin
QA / QC DIRECTOR

DATE: 02-06-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10862441-01-00-05

STANDARD HOMEOPATHIC
MADE IN USA SINCE 1903

Serious Adverse Event
SAE-0004-2015

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A22214, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A22214 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A22214. The Baby Teething bulk lot # 122944 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0617-2014) has been received for Hyland's Baby Teething Tablets lot # A22214. The complaints were reviewed and the complaints do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A22214.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

02-05-15
Date

DSS
FEB 20 2015

CC-0078-2015
AE-0043-2015

FEB 19 2015

10862441-01-00-06

SE EVENT DATA FORM

AE #: 1595 COMPLAINT #: 2605

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

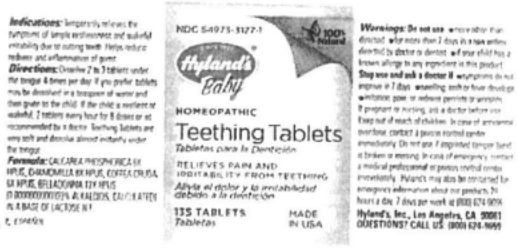
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 02-09-15

BY: DATE: 02-06-15

QA / QC DIRECTOR

DSS

FEB 20 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

FEB 19 2015

Individual Case Safety Report

10866401-01-00-01

umer Report

RY reporting of
luct problems and
use errors

CaseID: 10866401

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence #
584023

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	8 Months (b) (6)	☑ Female ☐ Male	17.5 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
02/18/2015	02/18/2015

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Hylands Baby Teething Tablets
Strength: 135 tab/bottle
Manufacturer: Hylands Inc.
#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 Up to 2 tabs every hour x6d	As needed	dissolved on tongue
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 1 dose of 2 tabs then hx3d
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	B01614
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

CTU
FEB 19 2015

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
19 2015

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. **Describe Event or Problem** *(continued)*

I bought Hylands Teething Tablets today at the local Rite Aid. I gave my 8 month old foster child 2 tabs then 1 tab every two hours for teething. On the package it says may give 2 tabs every hour for up to 6 doses. After the first dose I noticed her flushing. She seemed to get some relief. I gave her 1 more dose, she acted cranky and tired but stopped chewing on anything she could fit in her mouth. I gave her a third dose. She acted "weird", like slow, drugged.I noticed she seemed to have trouble breathing, just for a few seconds. I didn't know if I had imagined it. I didn't relate it to the medicine as the package says it is a SAFE SOLUTION and homeopathic. I gave her one more dose. Within 10 minutes she was flushed and her pupils were dilated and then she did the breathing thing again. All symptoms relieved after about 30 min and I did not feel the need to get medical intervention. I have been checking her breathing frequently. I found a video from the FDA on the dangers of giving this product. I will not give it again. Why is it still being sold?

Individual Case Safety Report

10866401-01-00-02

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race:White
Medical Conditions: Was born with addictions to opiates and benzodiazipans. Wonder if this is related.

Allergies: none known at this time.

Important Information: She is my foster child.

RX Meds: None

OTC Meds: Tylenol/ motrin

Individual Case Safety Report

10866401-01-00-03

CaseID: 10877680

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

10877680-01-00-01

...ıser-facilities,
...ırs and manufacturers
...ORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

FDA Use Only

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	or _____	☑ Female	_____ lbs
In confidence	Date of Birth:	☐ Male	or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
08/12/2012	02/05/2015

5. Describe Event or Problem

ON AUGUST 6, 2012, DAUGHTER STARTED TAKING THE BABY TEETHING TABLETS. AUGUST 12TH CHILD HAD A SEIZURE LASTING 20 MIN. CHILD NEVER HAD A SEIZURE PRIOR TO USING THE TABLETS. CHILD CONTINUED USING TABLETS AND HAD 4 MORE SEIZURES SOME LASTING OVER AN HOUR. AFTER DISCONTINUING THE BABY TEETHING TABLETS CHILD HAS NOT HAD ANY MORE SEIZURES.

RECEIVED
FEB 24 2015
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNKNOWN

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 UNKNOWN DOSAGE	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF TEETHING PAIN	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☑ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

EIB 02-10-15

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Unique Identifier (UDI) #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
FEB 25 2015

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

USA

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

FEB 24 2015

PLEASE TYPE OR USE BLACK INK

CaseID: 10877680

10877680-01-00-02

of 5

FDA USE ONLY

1. Check One
☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
EDYTA FRACKIEWICZ
Address
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address
STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
01/31/2015

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/ 510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973 AE #1598

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
FEB 25 2015

FEB 24 2015

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

MPLAINT RECORD

10877680-01-00-03

COMPLAINT #: 2608

DATE OF COMPLAINT: 01/31/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS ITEM CODE: BTET

SIZE: N/A LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING MESSAGE ON (b) (6) AND DID NOT RESPOND TO TWO REQUESTS TO CONTACT HYLAND'S: I STRONGLY SUGGEST YOU FIND ANOTHER SOLUTION. THESE TABLETS ARE NOT JUST SUGAR PILLS. AMONG OTHER THINGS THEY CONTAIN BELLA DONNA (A POISON) WHICH SUPPOSEDLY IS OK IN SMALL DOSES. IN 2010, THE FDA SHOWED HYLAND'S TEETHING TABLETS DID NOT HAVE A CONTROLLED WAY OF ENSURING LOW LEVELS OF THE BELLA DONNA AND ISSUED A RECALL. THE TABLETS HAD INCONSISTENT AMOUNTS OF IT. THEY SAY THEY HAVE CORRECTED THIS BUT WE DON'T FIND THAT TO BE TRUE. SIDE EFFECTS OF B.D. ARE SEIZURES AMONG OTHER THINGS. ON AUGUST 6, 2012, MY DAUGHTER STARTED TAKING THESE. AUGUST 12TH SHE HAD A SEIZURE LASTING 20 MIN. WE DID NOT MAKE A CONNECTION BETWEEN THE TABLETS AND SEIZURE, ALTHOUGH SHE HAD NEVER HAD ONE BEFORE AND THE TABLETS WERE THE ONLY VARIABLE. CONTINUED TAKING THEM, HAD 4 MORE SEIZURES SOME LASTING OVER AN HOUR! SHE HAD NOT HAD A SEIZURE SINCE STOPPING THE TABLETS, OVER A YEAR AND A HALF.
HTTP://WWW.FDA.GOV..../PRESSANNOUNCEMENTS.UCM230761.HTM

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 01/31/15

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1598

DSS
FEB 25 2015

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 01/31/15 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 02-12-15

BY: QA / QC DIRECTOR DATE: 02-10-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

FEB 24 2015

10877680-01-00-04

NDARD
PATHIC
USA SINCE 1903

Serious Adverse Event
SAE-0007-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty eight (138) Adverse Events (AE) which also included forty four (44) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤ (b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

02-06-15
Date

DSS
FEB 25 2015

FEB 24 2015

10877680-01-00-05

SE EVENT DATA FORM

AE #: 1598 COMPLAINT #: 2608

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

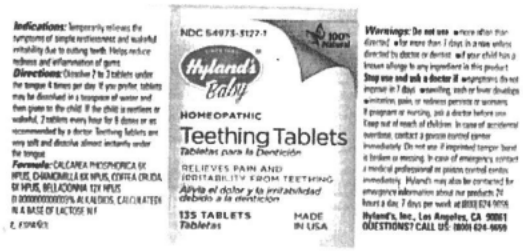
COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

DSS
FEB 25 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 02-12-15

BY: QA / QC DIRECTOR DATE: 02-10-15 FEB 24 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

10901130-01-00-01

CaseID: 10901130

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

user-facilities,
tors and manufacturers
TORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	3 Years	☑ Female ☐ Male	____ lbs or ____ kgs
In confidence	or Date of Birth:		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
00/00/0000	02/09/2015

5. Describe Event or Problem

MESSAGE POSTED ON (b) (6) REPORTING THAT CHILD HAD A SEIZURE WHILE USING BABY TEETHING TABLETS.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNKNOWN

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 UNKNOWN DOSAGE	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

MAR 03 2015

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

CDR

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

MAR - 4 2015

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

MAR - 3 2015

MAR - 3 2015

ILSA

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

10901130-01-00-02

FDA USE ONLY

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: EDYTA FRACKIEWICZ
Address: HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address: STANDARD@HYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 02/05/2015

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): SEIZURE

9. Manufacturer Report Number: 54973 AE # 1599

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
MAR - 4 2015

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

MAR - 3 2015

10901130-01-00-03

COMPLAINT #: 2609

DATE OF COMPLAINT: 02/05/15

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: N/A

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING TWO MESSAGES ON (b) (6) AND DID NOT RESPOND TO HYLAND'S REQUEST TO CONTACT US: I USE THE TEETHING TABLETS AND MY KID WENT INTO SEIZUREW BUT MY DAUGHTER DOC TOLD US TRY THEM BECAUSE SHE THREE AND JUSGOT ALL HER TEETH.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 02/05/15

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1599

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 02/05/15 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 02-18-15

BY: QA / QC DIRECTOR DATE: 02-17-15

DSS MAR - 4 2015

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

MAR - 3 2015

10901130-01-00-04

VDARD
ATHIC
BA SINCE 1903

Serious Adverse Event
SAE-0008-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty nine (139) Adverse Events (AE) which also included forty five (45) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

2/13/15
Date

DSS
MAR - 4 2015

MAR - 3 2015

10901130-01-00-05

10901130

ISE EVENT DATA FORM

AE #: 1599 COMPLAINT #: 2609

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: STATE:

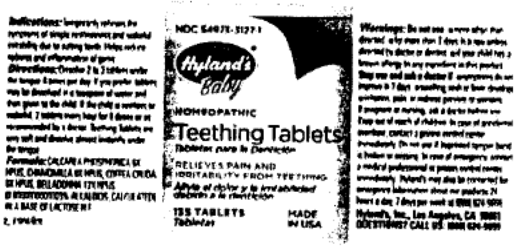
COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

DSS

REVIEWED BY MANAGEMENT BY: Robert Joy DATE: 02-18- MAR - 4 2015

BY: Eric Baun DATE: 02-17-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

MAR - 3 2015

FORM SAE01

Individual Case Safety Report

10945484-01-00-01

CaseID: 10945484

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

user-facilities,
tors and manufacturers
TORY reporting

Mfr Report #

UF/Importer Report #

OTC

FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	3 Months	☐ Female	____ lbs
In confidence	or ____ Date of Birth:	☑ Male	or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
02/25/2015	03/03/2015

5. Describe Event or Problem

3 MONTH OLD BABY DEVELOPED DIFFICULTY BREATHING 6 HOURS AFTER RECEIVING ONE TABLET OF BABY TEETHING TABLETS. HE HAS A HISTORY OF ASTHMA AT BIRTH, THAT HAS NOT RECURRED LATELY AFTER TREATMENT WITH PROAIR ALBUTEROL.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

ASTHMA AT BIRTH

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1 TABLET ONCE ORALLY	#1
#2	#2

RECEIVED
MAR 18 2015
CDR

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEMP RELIEF OF TEETHING SX	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A08815	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

PROAIR ALBUTEROL

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Unique Identifier (UDI) #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

(b) (6) USA

DSS
MAR 19 2015

Phone #	Email Address
(b) (6)	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

MAR 18 2015

Individual Case Safety Report

CaseID: 10945484

10945484-01-00-02

FDA USE ONLY

1. Check One
☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
EDYTA FRACKIEWICZ
Address
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address
STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
02/25/2015

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
WHEEZING, SHORTNESS OF BREATH

9. Manufacturer Report Number
54973 AE # 1601

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
MAR 19 2015
MAR 18 2015

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

10945484-01-00-03

PLAINT RECORD

Ca...5484

COMPLAINT #: 2611

DATE OF COMPLAINT: 02/25/15

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: A08815

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: 3 MONTH OLD BABY DEVELOPED DIFFICULTY BREATHING 6 HOURS AFTER RECEIVING ONE TABLET OF BABY TEETHING TABLETS. HE HAS A HISTORY OF ASTHMA AT BIRTH, THAT HAS NOT RECURRED LATELY AFTER TREATMENT WITH PROAIR ALBUTEROL. HIS SYMPTONS OCCURRED EARLY THIS MORNING AT 4 AM WITH WHEEZING, CONGESTION AND SHORTNESS OF BREATH, "NOT UNLIKE HIS ASTHMA SYMPTOMS". THE MOTHER REPORTED THAT HE "NEEDED TO BE MAKING NOISES IN BETWEEN BREATHS IN ORDER TO FACILITATE BREATHING". HE WAS GIVEN PROAIR AT HOME, BUT IT DID NOT SEEM TO HELP HIM AS IT HAD PREVIOUSLY FOR HIS ASTHMA. A DOCTOR WAS CALLED BUT NOT YET REACHED. I SUGGESTED CALLING THE DOCTOR AGAIN, OR TO CALL 911 IF HIS BREATHING WORSENED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 02/25/15

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1601

ADVERSE EVENT SERIOUS: (Y) / N

DSS

MAR 19 2015

ADVERSE EVENT REPORTED ON: 02/25/15

BY: TUTTI GOULD

MAR 18 2015

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 03-04-15

BY: Eric Bain
QA / QC DIRECTOR

DATE: 03-03-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10945484-01-00-04

NDARD
PATHIC
USA SINCE 1993

Serious Adverse Event
SAE-0010-2015

Product in Inventory:

Twenty (20) units of Hyland's Baby Teething Tablets (BTET), lot # A08815, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A08815 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A08815. The Baby Teething bulk lot # 124034 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b) (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product. Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # A08815. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A08815.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

03-03-15
Date

DSS
MAR 19 2015
MAR 18 2015

CC-0174-2015
AE-0094-2015

Individual Case Safety Report

10945484

10945484-01-00-05

Hyland's

SE EVENT DATA FORM

AE #: 1601 **COMPLAINT #:** 2611

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

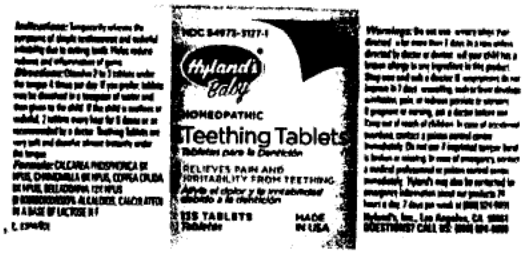
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE: DSS MAR 19 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Wells DATE: 03-04-15

BY: Eric Baum DATE: 03-03-15 MAR 19 2015

QA / QC DIRECTOR

MAR 18 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

10984052-01-00-01

CaseID: 10984052

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...ıser-facilities,
...ırs and manufacturers
...ORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	or	☑ Female ☐ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
05/00/2014 -- PRESENT	03/12/2015

5. Describe Event or Problem

MOTHER INITIALLY HAD POSTED ON (b) (6) THAT HER DAUGHTER HAD A SEVERE ALLERGIC REACTION. THEN OVER MONTH LATER SENT AN UPDATE AND PRODUCT CLARIFICATION VIA E-MAIL. CHILD GIVEN HYLAND'S BABY TEETHING TABLETS AND IN MAY 2014 DEVELOPED SEVERE BLISTERING FROM HER MOUTH THROUGH HER ENTIRE DIGESTIVE TRACT TO HER ANUS. BLISTERING CAUSED BLEEDING INSIDE OF HER MOUTH. SHE HAD BLOOD IN HER STOOL AS WELL AS BLISTERS THAT POPPED ON HER BUTTOCKS. CHILD REFUSED TO EVACUATE DUE TO PAIN AND IT TOOK OVER A MONTH FOR THE BLISTERS TO HEAL. CHILD CONTINUES TO HAVE HEMORRHOIDS INSIDE OF THE ANUS AND HAS DIFFICULTY HAVING BOWEL MOVEMENTS. CHILD ON SPECIAL DIET, STOOL SOFTENERS AND MIRALAX.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

HAS BEEN TO DOCTORS MULTIPLE TIMES.
CHILD ON SPECIAL DIET, STOOL SOFTENERS AND MIRALAX.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used

#1

#2

RECEIVED

3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*

#1

#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF TEETHING PAIN

#2

APR 01 2015

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1

#2

CDR

7. Exp. Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

APR - 2 2015

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

USA APR - 1 2015

Phone #

Email Address (b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

10984052-01-00-02

FDA USE ONLY

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home ☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
EDYTA FRACKIEWICZ
Address
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061
Email Address
STANDARD@HYLANDS.COM

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
03/10/2015

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/ 510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
ALLERGIC REACTION, GI BLISTERING, MOUTH BLISTERS, HEMORRHOIDS

9. Manufacturer Report Number
54973 AE # 1602

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/ Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

JSS

APR - 2 2015

APR - 1 2015

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

:OMPLAINT RECORD

Cas Hyland's 1052

10984052-01-00-03

COMPLAINT #: 2612

DATE OF COMPLAINT: 03/10/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: Na

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #:

E-MAIL: (b) (6)

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING COMMENT ON (b) (6) REGARDING BABY CALMING TABLETS ON 1/31/15: THESE ARE NOT JUST SUGAR PILLS. MY DAUGHTER HAD A SEVERE ALLERGIC REACTION TO THESE PILLS. CUSTOMER DID NOT RESPOND TO HYLAND'S REQUEST TO CONTACT US. ON 3/10/15 CUSTOMER SENT THE FOLLOWING E-MAIL WHICH PROVIDED CLARIFICATION THAT THE PRODUCT IN QUESTION WAS BABY TEETHING TABLETS AND THE ADVERSE EVENT WAS DETERMINED TO BE AN SAE. CUSTOMER DID NOT RESPOND TO HYLAND'S REGARDING TO CONTACT COMPANY BY PHONE: HI, I WAS CONTACTED BY CHRISTINE PHILLIPS VIA (b) (6) REGARDING THE ALLERGIC REACTION THAT MY DAUGHTER HAD TO YOUR PRODUCTS. IT HAPPENED IN MAY OF LAST YEAR AND WE ARE STILL DEALING WITH THE AFTER AFFECTS OF IT. SHE WAS GIVEN THE TEETHING TABLETS AND IT CAUSED SEVERE BLISTERING FROM HER MOUTH THROUGH HER ENTIRE DIGESTIVE TRACT TO HER ANUS. THE BLISTERING WAS SO SEVERE THAT SHE WAS BLEEDING INSIDE HER MOUTH. SHE HAD BLOOD IN HER STOOL AS WELL AS BLISTERS THAT POPPED ON HER BUTT SO SHE REFUSED TO HAVE HER DIAPER CHANGED. BECAUSE SHE WAS IN SO MUCH PAIN SHE THEN REFUSED TO GO TO THE BATHROOM AT ALL. IT TOOK OVER A MONTH FOR THE BLISTERS TO HEAL. SHE STILL HAS HEMORRHOIDS INSIDE OF HER ANUS. SHE STILL REFUSES TO TAKE A BOWL MOVEMENT ON A REGULAR BASIS BECAUSE SHE THINKS ITS GOING TO HURT. HER PEDIATRICIAN HAS BEEN WORKING WITH US TO GET HER BACK TO NORMAL SINCE WE GAVE HER THE TEETHING TABLETS. SHE HAS BEEN TO THE DOCTOR NUMEROUS TIMES BECAUSE OF THIS ISSUE AND HAS BEEN PLACED ON A SPECIAL DIET TO KEEP HER STOOLS SOFT SO THAT IT WILL BE LESS PAINFUL FOR HER TO GO TO THE BATHROOM. SHE ALSO HAS BEEN ON MIRALAX TO TRY AND MAKE IT EASIER FOR HER DUE TO THE HEMORRHOIDS. THIS HAS BEEN HORRIBLE FOR HER AND FOR US. IT IS VERY TRAUMATIC TO HAVE TO WATCH YOUR CHILD BE IN SUCH PAIN ON A REGULAR BASIS. THE PAIN OF HAVING TO GIVE HER SUPPOSITORIES AND ENEMAS IS TOO MUCH TO EVEN DESCRIBE. I JUST WONDER HOW MANY CHILDREN HAVE THE SAME ISSUE AND YOUR COMPANY IS AWARE OF IT AND DOES NOTHING ABOUT IT?

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 03/10/15

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ DSS

SECTION III: **CORRECTIVE ACTION:**

APR - 2 2015

APR - 2 2015

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1602

ADVERSE EVENT SERIOUS: (Y) / N

APR - 1 2015

ADVERSE EVENT REPORTED ON: 03/10/15 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWatt DATE: 03-19-15

BY: Eric Bain QA / QC DIRECTOR DATE: 03-16-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

10984052-01-00-04

NDARD PATHIC
USA SINCE 1903

Serious Adverse Event
SAE-0011-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty seven (137) Adverse Events (AE) which also included forty five (45) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(b)(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

3/16/15
Date

DSS
APR - 2 2015

APR - 1 2015

Individual Case Safety Report

10984052-01-00-05

10984052

EVENT DATA FORM

AE #: 1602 COMPLAINT #: 2612

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

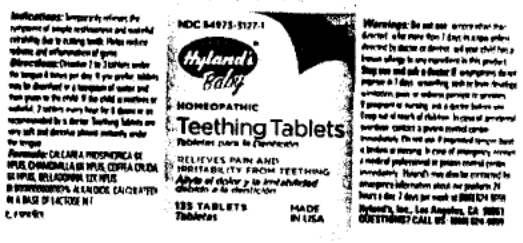
COUNTRY: USA ZIP CODE:

PHONE #:

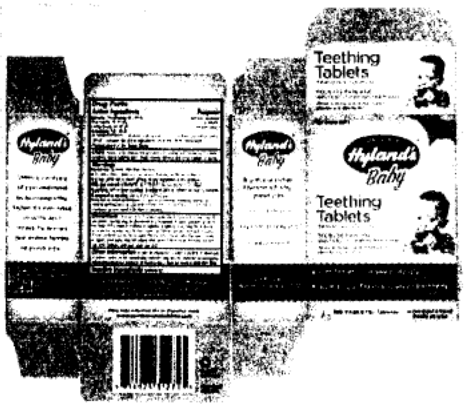
E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS

APR - 2 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 03-19-15 APR - 1 2015

BY: DATE: 03-16-15

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

CaseID: 10993411

1/2

10993411-01-00-01

...sumer Report

OTC

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

...RY reporting of
...duct problems and
product use errors

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY

Triage unit sequence #: 590752

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	10 Months (b) (6)	☐ Female ☑ Male	____ lb or ____ kg

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☑ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 occasionally for few months
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething pain
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/02/2015	04/03/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

See additional page(s) for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Name: Oragel Nighttime Formula
Strength:
Manufacturer: Oragel

#2 Name:
Strength:
Manufacturer:

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

APR - 6 2015

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

See additional page(s) for complete text.

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS

APR - 6 2015

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

I applied maximum strength oragel to my ten month old baby boys gums for teething pain. He had been crying for quite awhile, maybe an hour, even while I was applying it. I put a small amount on my finger and while trying to rub it on his gums I lost it. I didn't know if he swallowed it or it fell off my finger into our lap and blanket, but I didn't find it. I proceeded to try another small amount and succeeded in applying this dose to his gums. All the while he was still crying. Maybe a minute or even less later he went silent. I looked at his face and he was still crying but no noise or breath was coming out. He looked panicked. Then he went from red in the face, to purple, then blue, and finally white as his eyes rolled back in his head and he went limp. I panicked and ran outside for help from a neighbor while trying to dial 911. He was unresponsive for approximately 30 seconds and no breathing during this period either. Then as I ran across our street he began coming to. By the time the paramedics arrived he was regaining color, breathing and alert. They said his oxygen level and blood pressure was in the okay range so it was up to me if he went to the hospital or not. We opted out of the hospital but called the pediatrician who advised us to stop use of the oragel and to keep a close eye on him. We were lucky enough for our baby boy to return to normal by the end of the night.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

The paramedics tested his oxygen levels, heart rate and blood pressure which all were in okay levels at the time.

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Race: White

Medical Conditions:

Allergies:

Important Information:

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) *(continued)*

RX Meds:

OTC Meds: Vitamin D supplements for baby by enfamil