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:

11775061	11778980	11779071	11792162	11803222	11823505	11840826
11867472	11911253	12127275	12224038	12273905	12278506	12281261
12306511	12306848	12311125	12341669	12341756	12388846	12389148
12412557	12424787	12429653	12460888	12726345	12756114	

Run by: STEPPERH

Date - Time: 04-NOV-2016 08:49 AM

Total number of cases (Esub): 27

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11775061

Case Information:

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

FDA Rcvd Date: 24-Nov-2015 **Mfr Rcvd Date:** 11-Nov-2015 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1044595 **Application #:** 999999

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral				

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Â Version: 18.1)	ReC
Pyrexia	NA
Screaming	NA
Seizure	NA

Event/Problem Narrative:

MOTHER POSTED ON (b) (6) THAT SHE GAVE HER SON A TEETHING TABLET AND PUT HIM TO BED AND SHORTLY AFTER HE WOKE UP SCREAMING AND HAD A HIGH FEVER. SHE GAVE THE CHILD TYLENOL FOR THE FEVER AND WHILE LAYING HIM DOWN TO SLEEP HE HAD A MINI SEIZURE. CHILD WAS PUT IN A COLD BATH TO GET THE FEVER DOWN. SYMPTOMS RESOLVED AND HAVE NOT REOCCURRED.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11775061

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11778980

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 15-Nov-2015 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 25-Nov-2015 **Mfr Rcvd Date:** 15-Nov-2015 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1044659 **Application #:** 999999

Patient Information:

Age: 213 DAY **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		3 DF/	Oral				

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Dyskinesia	NA
Dyspnoea	NA
Muscle twitching	NA
Seizure	NA
Tremor	NA

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11778980

Event/Problem Narrative:

THE CUSTOMER REPORTS THAT HIS 7 MONTH OLD SON BEGAN TAKING BABY TEETHING TABLETS 3 DAYS AGO. APPROXIMATELY 24 HOURS AGO, THE CHILD BEGAN HAVING EPISODES OF SHAKING, TWITCHING AND MAKING ABNORMAL FACES. THE CUSTOMER ALSO REPORTS THAT HIS SON'S BREATHING HAS ALSO BEEN HEAVIER. THE LAST DOSE OF MEDICINE WAS GIVEN THIS MORNING AND THE CHILD EXPERIENCED ANOTHER EPISODE OF SHAKING ONE HOUR LATER. THERE ARE NO OTHER SYMPTOMS AT THIS TIME.

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
					N

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11778980

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11779071

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 2015 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 25-Nov-2015 **Mfr Rcvd Date:** 15-Nov-2015 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1044662 **Application #:** 999999

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething					PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk			54973-3127-3	STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Tremor	NA

Event/Problem Narrative:

REPORTER SENT AN E-MAIL STATING THAT HER SON HAS RECENTLY STARTED HAVING UNCONTROLLABLE SHAKING WHICH HAS OCCURRED AROUND THE TIME OF STARTING THE HYLAND'S BABY TEETHING TABLETS. HE IS SCHEDULED TO SEE A PEDIATRIC NEUROLOGIST IN THREE WEEKS.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11779071

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11792162

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** Jan-2015 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 01-Dec-2015 **Mfr Rcvd Date:** 13-Nov-2015 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1044881 **Application #:** 999999

Patient Information:

Age: 182 DAY **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk			54973-3127-1	STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Ear disorder	NA
Febrile convulsion	NA
Seizure	NA

Event/Problem Narrative:

CHILD HAD HIS FIRST SEIZURE AT THE AGE OF 6 MONTHS WHILE USING THE BABY TEETHING TABLETS AND ALSO HAD A SLIGHT FEVER AT THE TIME. HE WAS DIAGNOSED WITH A FEBRILE SEIZURE BUT CHILD DOES NOT GET HIGH TEMEPERATURES BECAUSE THEY ARE AROUND 100 DEG. FAHRENHEIT. WHEN HE HAS THE SEIZURE HE STARTS SHAKING, TWITCHING, JERKING, DROOLING IN THE MOUTH, EARS TURN PURPLE. SOMETIMES HE HAS SEIZURES WITHOUT A FEVER. CHILD IS NOW 16 MONTHS OLD AND ON KEPPRA. CHILD ALSO USES THE BABY GAS DROPS.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11792162

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
					N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	INFANTS GAS DROPS	.3 ML/	Oral					

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11803222

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 25-Nov-2015 **Outcomes:** LT **Application Type:** NDA

FDA Rcvd Date: 04-Dec-2015 **Mfr Rcvd Date:** 25-Nov-2015 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1045081 **Application #:** 999999

Patient Information:

Age: 91 DAY **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk			54973-3127-3	STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Cardio-respiratory arrest	NA
Cyanosis	NA
Respiratory arrest	NA
Unresponsive to stimuli	NA

Case ID: 11803222

Event/Problem Narrative:

MOTHER GAVE THE CHILD 2 BABY TEETHING TABLETS ON (b) (6) FOR THE FIRST TIME AND LAID HIM DOWN IN THE BOUNCER SEAT AND (b) (6) LATER CHILD WAS NOT BREATHING AND UNRESPONSIVE. MOTHER JOSTLED HIM AND HE WOULD NOT WAKE UP. GAVE HIM CPR AND CALLED AN AMBULANCE. CHILD HAD ANOTHER EPISODE IN THE HOSPITAL WHERE HE TURNED BLUE AND AGAIN STOPPED BREATHING. CHILD WAS GIVEN A BARIUM SWALLOW TEST TO RULE OUT REFLUX, EKG, URINALYSIS, HEART ECHO AND ALL TESTS ARE NORMAL. DOCTORS BELIEVE SYMPTOMS RELATED TO USE OF BABY TEETHING TABLETS BECAUSE THEY CANNOT DETERMINE ANOTHER CAUSE ALTHOUGH THERE IS A SLIGHT POSSIBILITY THAT SYMPTOMS COULD BE DUE TO REFLUX.

Relevant Medical History:

BORN AT 36 WEEKS - SLIGHTLY PREMATURE. NO FAMILY HISTORY OF SEIZURES.

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
					N

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11803222

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11823505

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** Jul-2015 **Outcomes:** HO **Application Type:** NDA

FDA Rcvd Date: 10-Dec-2015 **Mfr Rcvd Date:** 03-Dec-2015 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1045316 **Application #:** 999999

Patient Information:

Age: 152 DAY **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		3 DF/	Oral		PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		Yes	Unk	A61115		54973-3127-2	STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Hypopnoea	NA
Seizure	NA

Event/Problem Narrative:

THE REPORTER'S 10-MONTH-OLD SON HAS BEEN USING THE "BABY TEETHING TABLETS" SINCE JULY. THE REPORTER STATED THAT THE CHILD HAS BEEN EXPERIENCING SEIZURES SINCE BEGINNING USE OF THE TABLETS. THE REPORTER STATED THAT THE CHILD HAD HIS FIRST SEIZURE "A COUPLE OF WEEKS" AFTER HIS FIRST DOSE OF THE "BABY TEETHING TABLETS." SHE STATED THAT SINCE THEN, HE HAS BEEN HOSPITALIZED 5 OR 6 TIMES WITH SEIZURES AND THAT THEY HAVE BEEN FORCED TO CALL AN AMBULANCE FOR HIM MULTIPLE TIMES. SHE STATED THAT SHE WOULD GIVE HIM AT MOST 2-3 TABLETS AT ONE TIME WHEN TEETHING SYMPTOMS WERE PRESENT AND THAT SHE WOULD DOSE HIM 1-2 TIMES PER DAY, DEPENDING ON THE SEVERITY OF THE SYMPTOMS. THE REPORTER STATED THAT HER SON WOULD BECOME FUSSY WITH TEETHING SYMPTOMS, SHE WOULD GIVE HIM A DOSE OF "BABY TEETHING TABLETS," AND THEN HE WOULD NURSE AND FALL ASLEEP. SHE STATED THAT ABOUT 30-45 MINUTES LATER, THE CHILD WOULD WAKE UP WITH A SEIZURE. SHE STATED THAT HE WOULD TENSE UP IN HIS SLEEP, AND THEN "HIS ENTIRE BODY WOULD SHAKE OR TREMOR REALLY

Case ID: 11823505

VIOLENTLY." SHE STATED THAT HIS MOUTH WOULD QUIVER AND HIS EYES WOULD ROLL UP TO THE LEFT OR RIGHT. SHE DESCRIBED HOW HE WOULD MAKE NOISES THAT SOUNDED AS IF HE WAS GASPING FOR BREATH AND THAT "A COUPLE OF TIMES HE STOPPED BREATHING AND WOULD TURN BLUE." SHE STATED THAT THE SEIZURES WOULD TYPICALLY LAST FOR ABOUT 2-3 MINUTES AND THAT SHE HAS THE SEIZURES ON VIDEO FOR MEDICAL PURPOSES. THE REPORTER DISCONTINUED USING THE "BABY TEETHING TABLETS" WITH HER SON ABOUT ONE MONTH AGO; HE HAS NOT HAS A SEIZURE SINCE DISCONTINUING USE OF THE PRODUCT. THE REPORTER STATED THAT THE CHILD'S BREATHING WOULD SLOW DOWN WHILE HE WAS SLEEPING, AS WELL. SHE STATED THAT IT WOULD SLOW TO THE POINT THAT IT APPEARED AS THOUGH HE WASN'T BREATHING FOR A FEW MINUTES, AND THEN HE WOULD "KIND OF GASP AND BE FINE." SHE STATED THAT THIS SYMPTOM HAS ALSO DISSIPATED SINCE DISCONTINUING USE OF THE "BABY TEETHING TABLETS." PER THE REPORTER, THE DOCTORS, INCLUDING NEUROLOGY SPECIALISTS, CANNOT FIND ANYTHING INDICATING A CAUSE FOR THE SEIZURES.

Relevant Medical History:

NO PRE-EXISTING CONDITIONS. THE CHILD IS EXCLUSIVELY BREAST-FED, AND THE MOTHER IS ON A STRICT DIET DUE TO BREAST-FEEDING. THE CHILD CURRENTLY HAS PRESCRIPTIONS FOR DIASTAT AND KLONOPIN; HE HAS NOT BEEN GIVEN THE DIASTAT AT HOME, BUT HE HAS BEEN GIVEN THE KLONOPIN TWICE. HE IS CURRENTLY TAKING NO OTHER MEDICATIONS.

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
					N

Concomitant Products:

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

Case ID: 11823505

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11840826

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 2015 **Outcomes:** OT, **Application Type:** NDA

FDA Rcvd Date: 16-Dec-2015 **Mfr Rcvd Date:** 07-Dec-2015 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1045556 **Application #:** 999999

Patient Information:

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

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething					PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	NA			54973-3127-3	STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Renal failure	NA

Event/Problem Narrative:

A HEALTH FOOD STORE EMPLOYEE REPORTED WHAT A CUSTOMER TOLD HER ON 12/04/15 WHILE IN THE STORE, (b) (6) THE CUSTOMER SAID HER 15 MONTH OLD DAUGHTER WAS DIAGNOSED WITH KIDNEY FAILURE AND WAS AT HOME PRESENTLY WAITING FOR A BED AT (b) (6) HOSPITAL. SHE SAID THE DOCTORS RELATED IT TO THE TEETHING TABLETS. WE DO NOT PRESENTLY HAVE THE NAME OR CONTACT INFORMATION OF THE MOTHER OR HER DAUGHTER.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11840826

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11867472

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 12-Dec-2015 **Outcomes:** HO **Application Type:** NDA

FDA Rcvd Date: 24-Dec-2015 **Mfr Rcvd Date:** 16-Dec-2015 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1045865 **Application #:** 999999

Patient Information:

Age: 1 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		2 DF/QD	Oral		PAIN	11-Dec-2015	11-Dec-2015

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	No				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA® Version: 18.1)	ReC
Dehydration	NA
Febrile convulsion	NA

Event/Problem Narrative:

MOTHER CALLED WANTING A REFUND OF $5 FOR BABY TEETHING TABLETS. SHE SAID HER 15 MONTH OLD SON HAD BEEN IN HOSPITAL FOR SEVERAL DAYS WITH SEIZURES, AND SHE HAD READ ON LINE THAT TEETHING TABLETS CAUSED THEM.
12/10/15 11 AM, HE RECEIVED 2 VACCINES: HEPATITIS A AND PNEUMOCOCCAL (NEW FOR HIM).
12/11/15 8:45 AM HE STARTED A FEVER IN THE MORNING AND MOTHER BROUGHT HIM TO THE DOCTOR WHO SAID HE WAS FINE AND RECOMMENDED TYLENOL.
12/11/15 AT 9 PM, HE HAD HIS FIRST AND ONLY DOSE OF 2 TABLETS OF BABY TEETHING TABLETS.
(b) (6) (b) (6) MOTHER CHECKED ON HIM AND FOUND HE WAS HAVING SEIZURES IN HIS SLEEP, WITH DIFFICULTY BREATHING, AND FACE TURNING BLUE. HIS FEVER WAS 104.8. HE WAS GIVEN MOUTH TO MOUTH RECUSCITATION AND TAKEN TO THE HOSPITAL.
(b) (6) IN HOSPITAL, HE HAD A SECOND SEIZURE AT 3:30 PM.
(b) (6) (b) (6) HE CONTINUED TO HAVE FEVERS WITH SPIKES UP TO 105.8 WHILE IN THE HOSPITAL.

Case ID: 11867472

Preferred Term (MedDRA Â Version: 19.0 **ReC**

HE WAS TESTED WITH CHEST X-RAY AND CAT SCAN (ALL NORMAL), AND WAS GIVEN IV FOR DEHYDRATION. DIAGNOSIS WAS : FEBRILE SEIZURES, CAUSE UNKNOWN. (b) (6) HE WAS RELEASED FROM HOSPITAL AT NIGHT AFTER 24 HOURS WITH NO FEVER.

Relevant Medical History:

THERE IS NO FAMILY HISTORY OF SEIZURES; HE HAS NO PRE-EXISTING CONDITIONS OR ALLERGIES.
12/10/15 11 AM, HE RECEIVED 2 VACCINES: HEPATITIS A AND PNEUMOCOCCAL.
HE HAD FEVER STARTING IN THE MORNING OF 12/11/15; IT CONTINUED UNTIL (b) (6) . IT RANGED FROM 102 F TO SPIKES UP TO 105.8 F.

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
Chest X-ray normal					N
CAT SCAN - NORMAL					N

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11867472

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11911253

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 30-Dec-2015 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 12-Jan-2016 **Mfr Rcvd Date:** 05-Jan-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1046405 **Application #:** 999999

Patient Information:

Age: 152 DAY **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk	B38216			STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Seizure	NA

Event/Problem Narrative:

CUSTOMER CALLED TO REPORT THAT HER GRANDDAUGHTER HAS BEEN EXPERIENCING SHAKING AND TWITCHING WHICH APPEARS TO BE A SEIZURE. SHE IS GOING TO A NEUROLOGIST THIS WEEK FOR A DIAGNOSIS AND EVALUATION. WHILE THESE SYMPTOMS ARE OCCURRING THE CHILD MOVES HER HEAD AND ARMS A LOT. SOMETIMES SHE ACTS LIKE SHE IS LOST IN SPACE AND NOT RESPONDING. THE SYMPTOMS HAVE BEEN OCCURRING X 1 WEEK AND SHE HAD 3 EPISODES YESTERDAY.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11911253

Relevant Medical History:

NO RECENT IMMUNIZATIONS, NO FAMILY HISTORY OF SEIZURES, WAS NOT BORN PREMATURE.

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12127275

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 15-Feb-2016 **Outcomes:** HO,OT **Application Type:** NDA

FDA Rcvd Date: 29-Feb-2016 **Mfr Rcvd Date:** 15-Feb-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1048482 **Application #:** 999999

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething			Oral		TEETHING PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Seizure	NA

Event/Problem Narrative:

FATHER REPORTED ON (b) (6) THAT HIS SON HAS HAD TWO SEZIURES FOLLOWING THE USE OF BABY TEETHING TABLETS AND IS CURRENTLY HOSPITALIZED.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12127275

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12224038

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 10-Sep-2015 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 30-Mar-2016 **Mfr Rcvd Date:** 23-Mar-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1049998 **Application #:** 999999

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN	10-Sep-2015	10-Sep-2015

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		Unk	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Seizure	NA

Event/Problem Narrative:

HYLAND'S RECEIVED WRITTEN CORRESPONDENCE THAT A CHILD EXPERIENCED A SEIZURE AFTER INGESTION OF A TABLET.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12224038

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12273905

Case Information:

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

FDA Rcvd Date: 15-Apr-2016 **Mfr Rcvd Date:** 04-Apr-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1050623 **Application #:** 999999

Patient Information:

Age: 1 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething			Oral		TEETHING PAIN		
2	HYLAND'S TEETHING GEL							

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk			54973-3127	STANDARD HOMEOPATHIC
2	HYLAND'S TEETHING GEL		Unk	Unk			54973-7521-2	

Event Information:

Preferred Term (MedDRA Â® Version: 18.1)	ReC
Drug withdrawal syndrome	NA
Petit mal epilepsy	NA
Seizure	NA

Case ID: 12273905

Event/Problem Narrative:

MOTHER SENT AN E-MAIL AND POSTED ONLINE THAT HER SON EXPERIENCED SEIZURES AFTER DISCONTINUING THE PRODUCTS. MOTHER REPORTED THAT CHILD WAS HAVING STARING SPELLS WHILE TAKING THE PRODUCT(S) AND AFTER SHE STOPPED GIVING THE PRODUCT(S) TO THE CHILD, HE WENT THROUGH A WITHDRAWAL AND STARTING HAVING SEIZURES THAT CAME ON MASSIVELY AT 50 TO 100 PER DAY FOR 3 WEEKS UNTIL THE CHILD'S DOCTOR'S APPOINTMENT AND THEN THEY SLOWED DOWN TO 20 TO 30 PER DAY.

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
					N

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12273905

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12278506

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 06-Apr-2016 **Outcomes:** LT, **Application Type:** NDA

FDA Rcvd Date: 18-Apr-2016 **Mfr Rcvd Date:** 06-Apr-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1050690 **Application #:** 999999

Patient Information:

Age: 2 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN	06-Apr-2016	06-Apr-2016

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk	B30715			STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Aspiration	NA
Choking	NA
Crying	NA
Dyspnoea	NA
Screaming	NA

Case ID: 12278506

Event/Problem Narrative:

MOTHER GAVE A TABLET AND CHILD STARTED TO CHOKE ON IT AND WAS COUGHING AND VISIBLY CHOKING. MOTHER HIT HIM ON THE BACK AND HE SCREAMED AND CRIED FOR A LONG TIME AND WAS BREATHING HARD. MOTHER IS NOT SURE IF THE CHILD SWALLOWED THE TABLET OR IF HE COULD HAVE ASPIRATED IT INTO HIS LUNGS. AT THE TIME OF THE CALL THE CHILD WAS SLEEPING VERY SOUNDLY AND BREATHING NORMALLY.

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
					N

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12278506

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12281261

Case Information:

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

FDA Rcvd Date: 19-Apr-2016 **Mfr Rcvd Date:** 07-Apr-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1050701 **Application #:** 999999

Patient Information:

Age: **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething			Oral		TEETHING PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		Unk	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Status epilepticus	NA

Event/Problem Narrative:

FATHER REPORTED VIA E-MAIL THAT HE HAD BEEN GIVING THE BABY TEETHING TABLETS TO HIS DAUGHTER AND SHE WAS DIAGNOSED WITH NON-CONVULSIVE EPILEPSY.

Case ID: 12281261

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12306511

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 10-Apr-2016 **Outcomes:** HO,OT **Application Type:** NDA

FDA Rcvd Date: 26-Apr-2016 **Mfr Rcvd Date:** 11-Apr-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1051026 **Application #:** 999999

Patient Information:

Age: 213 DAY **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething			Oral		TEETHING PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk	A24214			STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Seizure	NA

Event/Problem Narrative:

A BABY WAS GIVEN BABY TEETHING TABLETS, DEVELOPED SEIZURES AND HAS BEEN HOSPITALIZED SINCE APPROXIMATELY (b) (6) THE BABY WAS SEDATED IN THE HOSPITAL WITH MEDICATION TO CALM THE BABY DOWN. THE BABY REMAINS HOSPITALIZED.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12306511

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12306848

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 09-Apr-2016 **Outcomes:** HO **Application Type:** NDA

FDA Rcvd Date: 26-Apr-2016 **Mfr Rcvd Date:** 14-Apr-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1051032 **Application #:** 999999

Patient Information:

Age: 213 DAY **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN	15-Mar-2016	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		Unk	Unk	B38415			STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Â© Version: 18.1)	ReC
Cerebral haemorrhage	NA

Event/Problem Narrative:

THE REPORTER STATED THAT HER SON WAS RECENTLY HOSPITALIZED AFTER USING THE "BABY TEETHING TABLETS." REPORTER STATES SHE HAS BEEN ADMINISTERING 2 TABLETS OF BTET TWICE DAILY SINCE THE MIDDLE OF LAST MONTH (APPROX. 3/15/16). EARLY IN THE MORNING OF (b) (6) SHE NOTICED THAT THE CHILD'S HEAD LOOKED SWOLLEN. SHE ALSO FELT A SOFT KNOT ON THE CHILD'S HEAD. SHE TOOK HIM TO A LOCAL HOSPITAL. CHILD WAS TRANSFERRED TO A HOSPITAL IN (b) (6) (b) (6) WHERE THE DOCTORS DIAGNOSED CHILD'S CONDITION AS "BLEEDING ON HIS BRAIN." CHILD WAS DISCHARGED ON (b) (6) CHILD IS AT HOME NOW. SWELLING IS YET TO GO DOWN.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12306848

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12311125

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 19-Mar-2016 **Outcomes:** HO,OT **Application Type:** NDA

FDA Rcvd Date: 27-Apr-2016 **Mfr Rcvd Date:** 18-Apr-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1051095 **Application #:** 999999

Patient Information:

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

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN, BODY TEMPERATURE INCREASED		
2	HYLAND'S BABY TINY COLD TABLETS			Oral				

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk	B51715			STANDARD HOMEOPATHIC
2	HYLAND'S BABY TINY COLD TABLETS		NA	Unk				

Event Information:

Preferred Term (MedDRA Version: 18.1)	ReC
Seizure	NA

Case ID: 12311125

Event/Problem Narrative:

CHILD WAS HOSPITALIZED (b) (6) FOR SEIZURES. CUSTOMER STATED THAT CHILD STARTED HAVING SEIZURES A MONTH AGO. LAST USE OF TEETHING TABLETS AND TINY COLD TABLETS PRIOR TO THE THE FIRST SEIZURE OCCURRING WAS 2-3 WEEKS. SEIZURES LOOKED LIKE STARING SPELLS WITH UPPER BODY CONVULSIONS LASTING 10 SECONDS AND TAKING ABOUT 20 MINUTES FOR CHILD TO RETURN TO NORMAL. CHILD HAS HAD A TOTAL OF THREE SEIZURES AND THE CHILD WAS HOSPITALIZED AFTER THE THIRD SEIZURE. DOCTORS UNABLE TO DETERMINE A CAUSE FOR THE SEIZURES.

Relevant Medical History:

DOCTORS OFFERED MEDICINE BUT MOTHER DECLINED. MOTHER IS TAKING THE CHILD BACK TO THE DOCTOR AND FOR A FOLLOW-UP VISIT WITH A NEUROLOGIST.

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
					N

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12311125

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12341669

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 20-Apr-2016 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 06-May-2016 **Mfr Rcvd Date:** 24-Apr-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1051563 **Application #:** 999999

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething			Oral		TEETHING PAIN	20-Apr-2016	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Â Version: 19.0)	ReC
Seizure	NA

Event/Problem Narrative:

MOTHER POSTED ON (b) (6) THAT HER SON HAD A SEIZURE AFTER TAKING THE TABLETS.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12341669

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12341756

Case Information:

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

FDA Rcvd Date: 06-May-2016 **Mfr Rcvd Date:** 26-Apr-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1051565 **Application #:** 999999

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething			Oral		TEETHING PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Generalised tonic-clonic seizure	NA

Event/Problem Narrative:

MOTHER POSTED ON (b) (6) THAT CHILD EXPERIENCED GRAND MAL SEIZURES THAT WERE TRACED BACK TO THE TEETHING TABLETS. AS PROOF PARENTS GAVE HIM ONE TABLET AND IN THE MATTER OF 15 MINUTES HE HAD A SEIZURE.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12341756

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12388846

Case Information:

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

FDA Rcvd Date: 20-May-2016 **Mfr Rcvd Date:** 06-May-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1052532 **Application #:** 999999

Patient Information:

Age: 1 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN, FEVER	Apr-2016	Apr-2016

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	No	B80015			STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Pyrexia	NA
Rash	NA
Seizure	NA
Vomiting	NA

Case ID: 12388846

Event/Problem Narrative:

CHILD WAS IN THE HOSPITAL FOR SEIZURES ABOUT A MONTH AGO WHEN MOTHER FIRST STARTED USING THE BABY TEETHING TABLETS. AT THE TIME OF THE HOSPITALIZATION THE CHILD HAD A FEVER OF 102.3 DEGREES. THE CHILD ALSO HAD A FEVER OF 101.2 DEGREES WITH RASH 2 DAYS AGO AND VOMITED YESTERDAY.

Relevant Medical History:

FATHER HAD SEIZURES WHEN HE WAS LITTLE.

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
					N

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12388846

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12389148

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 2016 **Outcomes:** HO **Application Type:** NDA

FDA Rcvd Date: 20-May-2016 **Mfr Rcvd Date:** 09-May-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1052539 **Application #:** 999999

Patient Information:

Age: 167 DAY **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	BABY TEETHING GEL (HYLAND HOMEOPATHIC)			Topical		TEETHING PAIN	2016	2016

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	BABY TEETHING GEL (HYLAND HOMEOPATHIC)		NA	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Seizure	NA

Event/Problem Narrative:

THE REPORTER'S SON, WHO IS 5.5 MONTHS OLD, HAS EXPERIENCED 4 SEIZURES SINCE BEGINNING USE OF THE "TEETHING GEL" PRODUCT. THE REPORTER BEGAN USING THE PRODUCT ON THE CHILD WHEN HE WAS "A LITTLE OVER 2 MONTHS OLD." SHE STATED THAT THEY USED THE PRODUCT AS NEEDED, EVERY TWO OR THREE DAYS. THE REPORTER STATED THAT SHE DID NOT USE THE PRODUCT DAILY. THE CHILD EXPERIENCED HIS FIRST SEIZURE AT THE AGE OF 3 MONTHS. THE REPORTER STATED THAT THE CHILD'S EYES ROLLED BACK INTO HIS HEAD, AND HE BECAME UNRESPONSIVE AND STIFF. SHE STATED THAT THIS EPISODE LASTED FOR 5 MINUTES. PER THE REPORTER, EACH OF THE CHILD'S 4 SEIZURES HAVE BEEN THE SAME. PER THE REPORTER, THE CHILD'S DOCTOR STATED THAT IT SOUNDS AS THOUGH THE CHILD IS HAVING SEIZURES; PER THE REPORTER, THE CHILD HAS HAD AN EEG AND A CT SCAN, BOTH OF WHICH HAVE BEEN NORMAL. THE CHILD HAS AN APPOINTMENT FOR AN MRI ON MAY 24TH; THE REPORTER STATED THAT THE MRI SHOULD GIVE THEM MORE INFORMATION THAN THE CT SCAN. PER THE REPORTER, THE DOCTOR

Case ID: 12389148

TOLD HER THAT THEY WERE "GOING TO LOOK FOR A CAUSE" OF THE SEIZURES. THE CHILD'S LAST SEIZURE OCCURRED ON (b) (6) THE REPORTER STATED THAT THEY WENT TO THE HOSPITAL ON THIS DATE AND THAT THEY DISCONTINUED USING THE PRODUCT ON THIS DATE.

Relevant Medical History:

SEASONAL ALLERGIES

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Seasonal allergy			

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
					N

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12389148

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12412557

Case Information:

Case Type: NON-EXPEDITED **eSub:** Y **HP:** **Country:** USA **Event Date:** 2009 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 08-Jun-2016 **Mfr Rcvd Date:** 11-Apr-2016 **Mfr Control #:** 54973 AE#1611 **Application #:** 999999

Patient Information:

Age: 152 DAY **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN	2009	2010

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Yes	105830			STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Seizure	NA

Event/Problem Narrative:

2009/2010 CHILD HAD FIVE SEIZURES ON SEPARATE OCCASIONS WHILE USING THE TEETHING TABLETS. FOUR OF THE SEIZURES WERE FEBRILE SEIZURES AND ONE WAS AN UNPROVOKED SEIZURE. CHILD'S FEVERS OCCURRED RAPIDLY. MOTHER BELIEVES THAT THE BELLADONNA MAY HAVE LOWERED THE CHILD'S SEIZURE THRESHOLD AND CONTRIBUTED TO HER SEIZURES. CHILD OUTGREW THE SEIZURES.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12412557

Relevant Medical History:

FAMILY HISTORY OF SEIZURES - TWO HALF-SIBLINGS FROM FATHER'S SIDE HAD FEBRILE SEIZURES AS INFANTS. CHILD HAD A FEVER FOR FOUR OF THE FIVE SEIZURES.

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12424787

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 2016 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 01-Jun-2016 **Mfr Rcvd Date:** 17-May-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1053003 **Application #:** 999999

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		Unk	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Seizure	NA

Event/Problem Narrative:

TARGET STORE REPORTED BY E-MAIL THAT CUSTOMER'S SON SUFFERED A SEIZURE AFTER TAKING A BABY TEETHING TABLET.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12424787

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12429653

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 20-May-2016 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 02-Jun-2016 **Mfr Rcvd Date:** 22-May-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1053119 **Application #:** 999999

Patient Information:

Age: 304 DAY **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Yes				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Â Version: 19.0)	ReC
Body temperature abnormal	NA
Flushing	NA
Muscle twitching	NA
Staring	NA
Unresponsive to stimuli	NA

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12429653

Event/Problem Narrative:

MOTHER GAVE CHILD A DOSE AT 2:45 PM FOR TEETHING PAIN. AT 4:30 PM CHILD SEEMED OUT OF IT, STARING OFF BLANKLY INTO THE ROOF, TWITCHING, AND UNRESPONSIVE TO MOTHER TALKING TO HIM, BRIGHT RED FLUSHED CHEEKS AND A TEMPERATURE. MOTHER WAS GOING TO TAKE CHILD TO THE HOSPITAL, HOWEVER SYMPTOMS RESOLVED AND CHILD ONLY REMAINED TIRED AND FLUSHED. SYMPTOMS OCCURRED ONCE AGAIN THE FOLLOWING DAY AFTER TAKING 2 TABLETS AND SUBSEQUENTLY RESOLVED.

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
					N

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12429653

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12460888

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 2016 **Outcomes:** HO,OT **Application Type:** NDA

FDA Rcvd Date: 13-Jun-2016 **Mfr Rcvd Date:** 30-May-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1053730 **Application #:** 999999

Patient Information:

Age: 152 DAY **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEMPERATURE INCREASED, TEETHING PAIN	Mar-2016	Apr-2016

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	NA				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Seizure	NA

Event/Problem Narrative:

CUSTOMER'S SON WAS DIAGNOSED WITH SEIZURES 1 MONTH AGO WHILE TAKING BABY TEETHING TABLETS. HE HAS SINCE DISCONTINUED THE TABLETS AND CONTINUES TO HAVE SEIZURES AND IS TAKING KEPPRA. HE WAS HOSPITALIZED FOR 1 WEEK DUE TO THE SEIZURES AND IN THE HOSPITAL HE WAS HOOKED UP TO AN EEG MACHINE WHICH FOUND SEIZURES ON ONE SIDE OF HIS BRAIN. DOCTORS UNSURE WHAT IS CAUSING THE SEIZURES.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12460888

Relevant Medical History:

NOT BORN PREMATURE, NO FAMILY HISTORY OF SEIZURES.

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12726345

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** Jun-2016 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 08-Sep-2016 **Mfr Rcvd Date:** 26-Aug-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1057183 **Application #:** 999999

Patient Information:

Age: 182 DAY **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		BODY TEMPERATURE INCREASED, TEETHING PAIN	Jun-2016	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk				STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Seizure	NA

Event/Problem Narrative:

MOTHER STATES THAT WITHIN (b) (6) HOURS OF USING THE BABY TEETHING TABLETS FOR THE FIRST TIME CHILD HAD A SEIZURE. ALL TOGETHER CHILD HAD 4 SEIZURES- ONE IN (b) (6) TWO IN (b) (6) AND ONE IN (b) (6) CHILD WAS TAKEN TO CHILDREN'S HOSPITAL. THE MORNING THAT CHILD WENT TO THE HOSPITAL ER, SHE WAS GIVEN BTET AND WITHIN A COUPLE OF HOURS SHE HAD A SEIZURE. EACH SEIZURE HAPPENED WHILE CHILD WAS NURSING OR FALLING ASLEEP; CHILD CLAMPED DOWN, GOT STIFF AND RIGID AND STARTED TO SHAKE. MOTHER WOULD GENTLY SHAKE HER AND SHE WOULD WAKE UP. AFTER MOTHER DISCONTINUED THE TABLETS, THE SEIZURES STOPPED.

Case ID: 12726345

Relevant Medical History:

WENT TO CHILDREN'S HOSPITAL ER FOR EVALUATION. DOCTOR CAME UP WITH A DIAGNOSIS OF SEIZURES BY QUESTIONING BECAUSE IT WAS TOO LATE TO DO AN EEG AS CHILD WAS NOT EXPERIENCING SEIZURES WHILE IN THE HOSPITAL. ACID REFLUX ON OCCASION. NO FAMILY HISTORY OF SEIZURES.

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
					N

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: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12756114

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 05-Sep-2016 **Outcomes:** LT **Application Type:** NDA

FDA Rcvd Date: 16-Sep-2016 **Mfr Rcvd Date:** 05-Sep-2016 **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1057400 **Application #:** 999999

Patient Information:

Age: 152 DAY **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Baby Teething		1 DF/	Oral		TEETHING PAIN	05-Sep-2016	
2	GRIPE WATER (DIETARY SUPPLEMENT)			Oral			05-Sep-2016	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Baby Teething		NA	Unk				STANDARD HOMEOPATHIC
2	GRIPE WATER (DIETARY SUPPLEMENT)		NA	Unk				

Event Information:

Preferred Term (MedDRA Â® Version: 19.0)	ReC
Choking	NA
Dysphagia	NA

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12756114

Event/Problem Narrative:

CUSTOMER REPORTED ON (b) (6) AND BY E-MAIL THAT CHILD WAS GIVEN BABY TEETHING TABLETS AND SHORTLY THEREAFTER WAS GIVEN GRIPE WATER AND SHE CHOKED ON THE GRIPE WATER. CHILD'S FACE TURNED COLORS AND SHE COULD NOT CATCH HER BREATH. PARENTS CALLED 911 FOR ASSISTANCE. PARENTS BELIEVE THAT BABY TEETHING TABLETS NUMBED THE CHILD'S THROAT AND CAUSED DIFFICULTY SWALLOWING.

Relevant Medical History:

CHILD WAS ALSO ADMINISTERED UNKNOWN BRAND OF GRIPE WATER (NO PRIOR REACTIONS TO GRIPE WATER).

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
					N

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12756114

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

Printer: CDPEDQ5
User: STEPPERH
Date - Time: 04-Nov-2016 08:50 AM
Total Number of Cases (Non-Esub): 65
Total Number of Pages: 253
Print Job Number: 12987

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.

Processed Case Id's for Images:
11008869 11012660 11061630 11088037 11090548 11145186 11173807 11176579
11179757 11179760 11179773 11179851 11188555 11254142 11258215
11275465 11275478 11279245 11301071 11364562 11374329 11395428 11415807
11419862 11468448 11473233 11500192 11513415 11516350 11516352
11516354 11516357 11516369 11516392 11516404 11516539 11516540 11516601
11536908 11544456 11603023 11614860 11614940 11628084 11639546
11658849 11683168 11699938 11700316 11788548 11788578 11878433 11999660
12009242 12079943 12197698 12470569 12480346 12491395 12606520
12654615 12689440 12693124 12720370 12721292

Failed Case Id's for Images:

Total Failed Cases: 0

CaseID: 11008869

Individual Case Safety Report

11008869-01-00-01

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 #

UF/Importer Report #

OTC

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	8 Months 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)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ 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)*
03/13/2015	03/26/2015

5. Describe Event or Problem

CHILD HAD A SEIZURE THE MORNING OF 03/13/15. NO PAST HISTORY OF SEIZURE. CHILD'S FIRST TIME USING THE TABLETS. MOTHER GAVE 2 TABS ON 03/10 AND 03/11 IN THE AM AND 1 TAB 03/12 IN THE AM. SEIZURE OCCURED IN THE BATHTUB AND GRANDMOTHER DESCRIBED IT AS CHILD LOSING BALANCE, EYES STARTED ROLLING IN THE BACK OF THE HEAD, DIFFICULTY BREATHING. SEIZURE LASTED ABOUT 5 - 7 MINUTES. FAMILY CALLED 911 AND SUBSEQUENTLY THE CHILD WAS FINE. CHILD WILL FOLLOW-UP WITH THE NEUROLOGIST.

(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.)*

GRANDFATHER'S BROTHER AND COUSIN HAVE 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.

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 2TABSLAM3/10&3/11;1TABSL

#2

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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 A08815

#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 #	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

DSS

APR - 9 2015

APR - 8 2015

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: 11008869

Individual Case Safety Report

11008869-01-00-02

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)*: 03/23/2015

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 # 1604

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
APR -9 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.

APR - 8 2015

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

Case 5243

SECTION I: COMPLAINT

COMPLAINT #: 2614

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 03/23/2015

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: CHILD HAD A SEIZURE THE MORNING OF MARCH 13. HAS NOT HAD A SEIZURE IN THE PAST. THIS WAS THE CHILD'S FIRST TIME USING THE TABLETS. MOTHER GAVE 2 TABLETS ON MARCH 10 AND 11 IN THE MORNING AND 1 TABLET ON MARCH 12 IN THE MORNING. SEIZURE OCCURRED IN THE BATHTUB AND GRANDMOTHER DESCRIBED IT AS CHILD LOSING BALANCE, EYES STARTED ROLLING IN THE BACK OF THE HEAD, DIFFICULTY BREATHING. THIS LASTED ABOUT 5 – 7 MINUTES. THEY CALLED 911 AND THE CHILD WAS FINE. FOLLOWED UP WITH THE DOCTOR AND CHILD HAS AN APPOINTMENT WITH THE NEUROLOGIST. GRANDFATHER'S BROTHER AND COUSIN HAVE HISTORY OF 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)

Individual Case Safety Report

11008869-01-00-03

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: 03/23/15

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 #: 1604

ADVERSE EVENT SERIOUS: (Y) / N

DSS

ADVERSE EVENT REPORTED ON: 03/23/15 BY: EDYTA FRACKIEWICZ

APR – 8 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: RWdtf DATE: 03-30-15

BY: Eric Baum QA / QC DIRECTOR DATE: 03-27-15

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

APR – 8 2015

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0013-2015

Product in Inventory:

No (0) 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 one other complaint has been received for Hyland's Baby Teething Tablets lot # A08815. The other complaint was also an SAE (SAE-0010-2015). The complaints were reviewed and although both complaints did indicate that the patient "had trouble breathing" they appear to be isolated and do not represent a trend. 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

3/26/15
Date

Individual Case Safety Report

11008869-01-00-04

DSS
APR - 9 2015

APR - 8 2015

CC-0251-2015
AE-0137-2015

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CaseID: 11008869

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1604 COMPLAINT #: 2614

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
11008869-01-00-05

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
APR - 9 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 03-30-15

BY: QA / QC DIRECTOR DATE: 03-27-15

APR - 8 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

CaseID: 11012660

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

11012660-01-00-01

...ıser-facilities,
...ors 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:	3. Sex	4. Weight
(b) (6)	5 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)*
03/19/2015	03/24/2015

5. Describe Event or Problem

MOTHER POSTED ON (b) (6) THAT HYLAND'S BABY TEETHING TABLETS DID NOT DISSOLVE, CHILD WAS CHOKING ON THEM, AND MOTHER HAD TO PERFORM THE HEIMLICH MANEUVER.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

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APR 09 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.)*

(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	#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: 54973-3127-1

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
APR 10 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 APR 2015

Phone # | Email Address

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

CaseID: 11012660

Individual Case Safety Report

11012660-01-00-02

: 5

FDA USE ONLY

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)*
03/19/2015

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)
CHOKING

9. Manufacturer Report Number
54973 AE # 1603

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
APR 10 2015

APR – 9 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."

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Case 11012660

SECTION I: COMPLAINT

COMPLAINT #: 2613

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: ~~2613~~ 03/19/15 03-31-15

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:

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (b) (6) ABOUT BABY TEETHING TABLETS AND DID NOT CONTACT HYLAND'S WITH MORE INFORMATION: THEY WERE NOT QUICK MELTING AT ALL! HAD TO GIVE MY 5 MONTH OLD THE HEIMLICH! SHE WAS CHOKING ON THEM! FURIOUS!

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: 03/19/15

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

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS
APR 10 2015

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1603

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 03/19/15

BY: EDYTA FRACKIEWICZ

SECTION V:

APR - 9 2015

REVIEWED BY MANAGEMENT BY:

DATE: 03-31-15

BY: QA / QC DIRECTOR

DATE: 03-30-15

Individual Case Safety Report

cc: QA / QC
Packaging

Form # VD1

11012660-01-00-03

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Serious Adverse Event
SAE-0012-2015

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. Although a lot number was not provided all BTET lots are tested for disintegration and typically disintegrate in less than 20 seconds.

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 six (46) 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

3/30/15
Date

Individual Case Safety Report
11012660-01-00-04

DSS
APR 10 2015

CC-0236-2015
AE-0131-2015

APR - 9 2015

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

C 11012660

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1603 COMPLAINT #: 2613

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

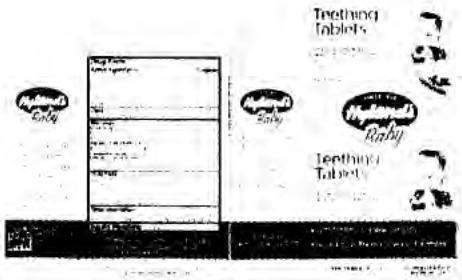
PHONE #:

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

11012660-01-00-05

SECTION III: CORRECTIVE ACTION:

DSS

APR 10 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: R E Wiltt DATE: 03-31-15

BY: Eric Baum DATE: 03-30-15
QA / QC DIRECTOR

APR - 9 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

11061630-01-00-01

CaseID: 11061630

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 #

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)	1 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)*
03/29/2015	04/07/2015

5. Describe Event or Problem

MOTHER AND AUNT POSTED ON (b) (6) THAT SHORTLY AFTER RECEIVING HYLAND'S BABY TEETHING TABLETS CHILD HAD A SEIZURE AND HAD TO BE ADMINISTERED CPR.

(Continue on page 3)

Received

APR 22 2015

CDR

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	#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)*

DSS

APR 23 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 22 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.

Individual Case Safety Report

CaseID: 11061630

11061630-01-00-02

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 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.	3. Report Source (Check all that apply)
04/03/2015	(A)NDA # ____ IND # ____ BLA # ____ PMA/ 510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes	☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
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	8. Adverse Event Term(s)
54973 AE # 1605	SEIZURE

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?	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. 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
APR 23 2015

APR 22 2015

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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.

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Individual Case Safety Report — COMPLAINT RECORD — Case [redacted] 630

11061630-01-00-03

COMPLAINT #: 2615

DATE OF COMPLAINT: 04/03/15

PRODUCT: HYLAND'S BABY TEETHING TABLETS — ITEM CODE: BTET---T135

SIZE: 135 TABLETS — LOT NO.: A41614

REPORTER: (b) (6)

ADDRESS:

CITY: — STATE: (b) (6)

COUNTRY: USA — ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: MOTHER POSTED THE FOLLOWING COMMENT ON HYLAND'S BABY TEETHING FACEBOOK PAGE: THIS PRODUCT MADE MY KID GET A SEIZURE LOOK INTO IT PLEASE!!! AUNT POSTED THE FOLLOWING COMMENT ON (b) (6) IF ANY OF YOU HAVE TEETHING BABIES OR HAVE USED THIS PRODUCT, PLEASE STOP THE USE... (b) (6) MY 1 YEAR OLD NEPHEW HAD A SEIZURE RIGHT AFTER HE WAS GIVEN THESE TABLETS (ONE OF THE SYMPTONS OF USING THIS PRODUCT, WAS UNAWARE UNTIL WE DID A SYMPTOM RESEARCH))!! PLEASE STOP THE USE, IT WAS THE SCARIEST THING EVER IN OUR LIVES!!! THANK GOD HE WAS AND IS OK, AND WITHOUT KNOWING IT WAS A SEIZURE, THAT MY MOM WAS THERE TO GIVE HIM CPR!!! PLEASE DO NOT USE!! WAS UNABLE TO SPEAK TO MOTHER OVER THE PHONE BECAUSE SHE DID NOT CALL OR PROVIDE A NUMBER WHERE SHE COULD BE REACHED. **04/10/15 FOLLOW-UP:** EDYTA FRACKIEWICZ SPOKE WITH MOTHER AND CHILD IS CURRETLY DOING WELL. ON THE DAY OF THE SEIZURE THEY CALLED PARAMEDICS AND WENT TO THE ER. DOCTOR'S NOT SURE WHY THE CHILD HAD A SEIZURE AND THEY WILL DO FOLLOW-UP TESTS. NO FEVER OR ILLNESS AT THE TIME OF THE SEIZURE AND NO FAMILY HISTORY OF SEIZURES. CHILD BECAME STIFF AND STOPPED BREATHING FOR 3 MINUTES DURING THE SEIZURE. OFFERED A REFUND AND CUSTOMER DECLINED. SHE REQUESTED THAT HYLAND'S BABY TEETHING TABLETS BE REMOVED FROM THE MARKET.

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: 04/03/15

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 #: 1605

DSS

APR 23 2015

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 04/03/15 — BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: — DATE: 04-16-15

BY: Eric Bain — DATE: 04-16-15

QA / QC DIRECTOR

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

Form # VD1

APR 22 2015

11061630-01-00-04

IDARD
ATHIC
A SINCE 1903

/erse Event

SAE-0014-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A41614, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the [redacted] units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A41614 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 # A41614. The Baby Teething bulk lot # 123302 was tested for total Atropine and Scopolamine and the results were with in specification of [redacted] 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-0846-2014) has been received for Hyland's Baby Teething Tablets lot # A41614. The complaints were reviewed but 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 # A41614.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

4/16/15
Date

DSS
APR 23 2015

APR 22 2015

Individual Case Safety Report

11061630-01-00-05

11061630

EVENT DATA FORM

AE #: 1605 COMPLAINT #: 2615

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
APR 23 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 04-16-15

BY: QA / QC DIRECTOR DATE: 04-16-15

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

APR 22 2015

CaseID: 11088037

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Individual Case Safety Report

11088037-01-00-01

...iser-facilities,
...ers and manufacturers
...ORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

FDA Use Only

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 ____	☑ 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)*
04/11/2015	04/16/2015

5. Describe Event or Problem

CUSTOMER SENT AN E-MAIL STATING THAT TEETHING TABLETS AND TEETHING GEL THICKENED THE SALIVA OF HER BABY AND MADE HIM CHOKE.

04/16/15 FOLLOW-UP: MOTHER REPORTED THAT CHILD HAD DIFFICULTY SWALLOWING AND THICK SALIVA WHICH CAUSED SEVERE CHOKING AND DIFFICULTY BREATHING. MOTHER LAID THE CHILD ON HIS SIDE ON THE FLOOR IN ORDER TO OPEN HIS AIRWAY AND ALMOST HAD TO PERFORM CPR.

Received

APR 29 2015

(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 KNOWN ALLERGIES, NO MEDICAL ISSUES, NO ILLNESS, NO FEVER, NOT 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 HYLAND'S BABY TEETHING GEL

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 2 TABS Q1HR X 2 DOSES	#1
#2 APPLIED TO GUMSBIDX1DAY	#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 SX PAIN, REDNESS	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 B37614	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 124181	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1 // 54973-7521-2

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
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

MAY -1 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.

APR 30 2015

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 11088037

11088037-01-00-02

FDA USE ONLY

6

☐ 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)*
04/11/2015

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)
THICK SALIVA, CHOKING

9. Manufacturer Report Number
54973 AE # 1606

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
MAY - 1 2015

APR 3 0 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.

STANDARD

CUSTOMER COMPLAINT RECORD

Case Number: 11088037

Individual Case Safety Report

11088037-01-00-03

COMPLAINT #: 2616

DATE OF COMPLAINT: 04/11/15

ITEM CODE: BTET---T135 / TGEL---U0.5Z

LOT NO.: B37614 // 124181

SIZE: 135 TABLETS / 0.5 OZ.

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: I BOUGH THE TEETHING GEL AND THE TEETHING TABLETS, BOTH YOUR BRANDS, AND I HAVE TO SAY THEY ARE DANGEROUS! THEY THICKENED THE SALIVA OF MY BABY AND MADE HIM CHOKE! THESE SHOULD COME WITH A WARNING ON THEM! **04/16/15 FOLLOW-UP:** SPOKE WITH CUSTOMER AND SHE INFORMED ME THAT CHILD HAD TROUBLE SWALLOWING AFTER USING BOTH TEETHING GEL AND BABY TEETHING TABLETS DUE TO THICK SALIVA WHICH HE STARTED CHOKING ON BOTH TIMES. CHOKING WAS SEVERE, SHE HAD TO LAY HIM ON HIS SIDE ON THE FLOOR AND OPEN HIS AIRWAY DUE TO DIFFICULTY BREATHING. ALMOST HAD TO PERFORM CPR. WILL RETURN THE PRODUCT TO THE STORE. NO MEDICAL ISSUES, NOT PREMATURE, NO KNOWN ALLERGIES, NO ILLNESS, NO FEVER. HAS AN APPOINTMENT TO SEE THE DOCTOR NEXT WEEK.

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:** 04/11/15

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 #: 1606

DSS

MAY - 1 2015

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 04/11/15 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: R Nutt DATE: 04-23-15

BY: QA / QC DIRECTOR DATE: 04-23-15

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

Form # VD1

APR 30 2015

Individual Case Safety Report

11088037-01-00-04

STANDARD HIC SINCE 1903

se Event
2015

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) & Hyland's Baby Teething Gel (TGEL) but no lot numbers, 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 two hundred seventeen (217) Adverse Events (AE) which also included fifty-one (51) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). There were nine (9) Adverse Events (AE) and only one (1) of them as elevated to an SAE for they Hyland's Teething Gel. 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 and TGEL lot numbers cannot be determined Standard Homeopathic Company does submit all Baby Teething 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

4/16/15
Date

DSS
MAY -1 2015

CC-0313-2015
AE-0175-2015

APR 30 2015

STANDARD

Individual Case Safety Report

11088037-01-00-05

11088037

T DATA FORM

AE #: 1606 **COMPLAINT #:** 2616

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

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

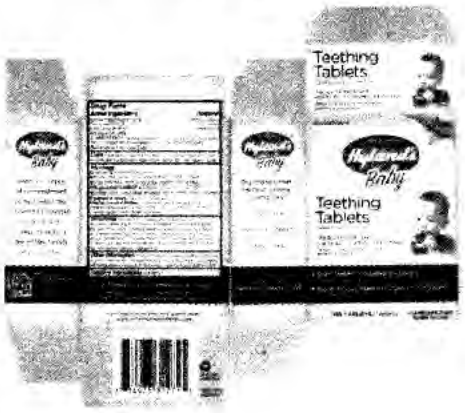
PHONE #: (b) (6)

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: MAY -1 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 04-23-15

BY: QA / QC DIRECTOR DATE: 04-23-15

DISTRIBUTION: FDA ADVERSE EVENT FILE

APR 30 2015

FORM

STANDARD HOMEOPATHIC

Individual Case Safety Report

11088037-01-00-06

11088037

T DATA FORM

COMPLAINT #: 2616

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

NDC 54973-7521-2
HOMEOPATHIC

Teething Gel
Gel para la dentición

Hyland's Baby

FAST RELIEF OF PAIN AND IRRITABILITY FROM TEETHING
Alivio rápido para el dolor y la irritabilidad debido a la dentición

0.5 FL. OZ. (14.7 mL)

Active ingredients: Calcarea Phosphorica 12X HPUS, Chamomilla 6X HPUS, Coffea Cruda 6X HPUS, Belladonna 6X HPUS (0.0000003% alkaloids, calculated).

Uses: Temporarily relieves symptoms of pain, gentle restlessness and wakeful irritability due to cutting teeth. Helps reduce redness and teething discomfort.

Warnings: **Do not use:** more often than directed **after** more than 7 days in a row unless directed by doctor or dentist **if** your child has a known allergy to any ingredient in this product. **Stop use and ask a doctor if:** symptoms do not improve in 7 days **swelling**, rash or fever develops **irritation**, pain or redness persist or worsen

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center immediately.

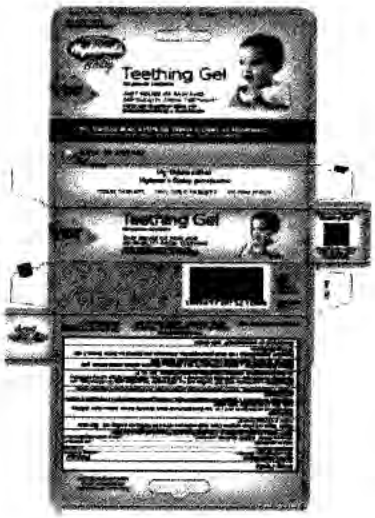
Directions: **wash** hands **cut** 1/8" off tip of tube to open **children under 3 years of age**, apply 1/4" ribbon to finger and rub carefully onto child's gums every 15 minutes as necessary **release** note: If your child has been crying or upset, your child may fall asleep after using this product because the pain has been relieved and your child can rest.

Other information: **do** not use if tube tip is broken or missing. **Hyland's** may also be contacted for emergency information about our products 24 hours a day, 7 days per week at (800) 624-9659.

Inactive ingredients: Citric Acid, Hydroxyethylcellulose, Potassium Sorbate, Purified Water, Sodium Benzoate, Sorbic Acid, Vegetable Glycerine.

Manufactured for: Hyland's, Inc., Los Angeles, CA 90031 www.hylandsbaby.com Rev. 003

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



SECTION III: **CORRECTIVE ACTION:**

DSS

MAY -1 201

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 04-23-15

BY: QA / QC DIRECTOR DATE: 04-23-15

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 30 2015

CaseID: 11090548

Individual Case Safety Report

Internet Consumer Report

OTC

CDER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

11090548-01-00-01

reporting of problems and errors

FDA USE ONLY

Triage unit sequence #

595065

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	Weight
(b) (6) In confidence	1 Years (b) (6)	☑ Female ☐ Male	21 lb or ____ kg

	Dose or Amount	Frequency	Route
#1	2-3 tablets 4x a day	Three times daily	Taken by mouth
#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 04/28/2015 – 04/30/2015
   #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 A24314	#1
#2	#2

9. NDC # or Unique ID
   A24314

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
05/01/2015	05/01/2015

5. Describe Event, Problem or Product Use Error
   See additional page(s) 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 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: Hylands teething tablets
Strength: 250 quick dissolve tablets
Manufacturer: Hylands

#2 Name:
Strength:
Manufacturer:

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU

2. Common Device Name

MAY – 4 2015

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 (b) (6) ZIP:

DSS

MAY – 4 2015

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)*

Hylands teething tablets. Noticed irritability, constipation, flushing from belladonna ingredient.

Individual Case Safety Report

11090548-01-00-02

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: Pollen

Important Information:

Individual Case Safety Report

11090548-01-00-03

Individual Case Safety Report

CaseID: 11145186

11145186-01-00-01

isumer Report OTC

ARY reporting of
oduct problems and
use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence #
598075

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	____ 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)*
05/21/2015	05/22/2015

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: HYLAND'S TEETHING TABLETS
Strength: N/A
Manufacturer: HYLAND'S

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 PILLS	As needed	Taken by mouth
#2		

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

4. Diagnosis or Reason for Use *(Indication)*
#1 EASE TEETHING DISCOMFORT
#2

6. Lot #	7. Expiration Date
#1	#1 05/22/2015
#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 26 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)

See additional page(s) for complete text.

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

1. Name and Address
Name: (b) (6)
Address:
City: State: ZIP:

DSS
MAY 26 201

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

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

11145186-01-00-02

Gave baby Hyland's Teething Tablets and he seemed to have side effects (slowed breathing, seizure-like shaking, and would stare off into space for a little bit). Only used them as needed (probably gave him about 10-16 tablets total). Ever since I stopped giving him the tablets, the symptoms subsided.

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

n/a

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: N/A

Allergies: N/A

Important Information: N/A

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

RX Meds: N/A

OTC Meds: N/A

11173807-01-00-01

by user-facilities,
butors and manufacturers
DATORY reporting

Mfr Report # 54973
UF/Importer Report #
OTC
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 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)*
- ☐ 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)*
04/00/2014	05/21/2015

5. Describe Event or Problem

MOTHER REPORTED THAT CHILD HAD BEEN USING THE PRODUCT FOR A COUPLE OF DAYS. ON THE DAY OF THE SEIZURE WAS GIVEN 1 TAB COUPLE OF HOURS PRIOR TO SEIZURE. THEN 1/2 - 1 HOUR PRIOR TO THE SEIZURE GAVE SECOND TABLET. THE SEIZURE LASTED 15 MINUTES AND HE WAS TRANSPORTED TO CHILDREN'S HOSPITAL. HE FELL OVER DURING THE SEIZURE, STOPPED BREATHING, ALSO VOMITED AND ASPIRATED DURING THE SEIZURE, HIT HIS HEAD WHEN HE FELL, AND EYES ROLLED BACK. CHILD HAD NO FEVER, BUT SEIZURE WAS LABELED BY DOCTORS AS FEBRILE SEIZURE.

RECEIVED
JUN 05 2015
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(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 FAMILY HISTORY OF SEIZURES. HAS HISTORY OF FLUID IN THE EARS AND HAD TUBES PLACED IN 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 TABS SL BID PRN X2DAYS	#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)
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.

DSS
JUN - 8 2015
JUN - 5 2015

CaseID: 11173807

11173807-01-00-02

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)*: 05/21/2015

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 # 1608

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 - 8 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."

JUN - 5 2015

CaseID: 11173807

11173807-01-00-03

COMPLAINT #: 2618

DATE OF COMPLAINT: 05/21/2015

PRODUCT: [illegible]

ITEM CODE: BTET

SIZE: NOT PROVIDED

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT:

MOTHER POSTED THE FOLLOWING COMMENTS ON (b) (6) DO NOT USE THESE. THESE CAN CAUSE SEIZURES. MY SON HAD A SEIZURE WHILE USING THESE AND HAD NEVER HAD ONE BEFORE HE USED THEM AND HASN'T HAD ONE SINCE HE STOPPED USING THEM. HE HAD ONLY HAD TWO TABLETS THAT DAY. NO I CAN'T SAY FOR COMPLETE CERTAINTY THIS WAS THE ONLY CAUSE BUT I STRONGLY BELIEVE IT WAS A CONTRIBUTING FACTOR. WE HADN'T SEEN THE RECALL ON THESE FOR SEVERAL WEEKS AFTER HIS SEIZURE BUT DIDN'T TAKE LONG TO CONNECT THE DOTS. THAT WAS IN 2014. THE MOST TABLETS HE HAD IN A DAY WAS FOUR BY THE WAY. I'M VERY CAUTIOUS ABOUT MEDS WITH MY CHILDREN. SPOKE WITH MOTHER ON 5/21/15: SHE REPORTED THAT SHE THREW AWAY THE BOTTLE IN 2014. SON NEVER HAD A SEIZURE IN THE PAST, AND THEN HAD A SEIZURE IN APRIL OF 2014. CHILD HAD NO FEVER, BUT WAS LABELED BY DOCTORS AS FEBRILE SEIZURE. SEVERAL WEEKS LATER SHE FOUND INFORMATION ABOUT THE RECALL. SHE HAD JUST STARTED USING BTET A COUPLE DAYS PRIOR (WAS USING ORAJEL BEFORE THEN). BOUGHT A NEW BOTTLE FOR THE CHILD. THE SEIZURE LASTED 15 MINUTES AND HE WAS TRANSPORTED TO CHILDREN'S HOSPITAL. HE FELL OVER DURING THE SEIZURE, STOPPED BREATHING, ALSO VOMITED AND ASPIRATED, HIT HIS HEAD WHEN HE FELL, AND EYES ROLLED BACK. WAS GIVEN 1 TAB COUPLE OF HOURS PRIOR TO SEIZURE. THEN 1/2 TO 1 HOUR PRIOR TO THE SEIZURE GAVE SECOND TABLET. CUSTOMER DID NOT WANT A REFUND.

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) N

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**: 05/21/2015

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 # 1608

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/21/2015

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 05-28-15

BY: Eric Bean
QA / QC DIRECTOR

DATE: 05-27-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

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JUN 5 2015

Form 3 V0

11173807-01-00-04

NDARD
PATHIC
USA SINCE 1903

Serious Adverse Event
SAE-0017-2015

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 forty-three (143) Adverse Events (AE) which also included fifty-two (52) 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

5/26/15
Date

DSS
JUN - 8 201

CC-0418-2015
AE-0230-2015

JUN - 5 2015

11173807-01-00-05

SE EVENT DATA FORM

AE #: 1608 COMPLAINT #: 2618

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: 05-28-15

BY: QA / QC DIRECTOR DATE: 05-27-15

DS

JUN - 8

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM 3260A

JUN - 5 2015

11176579-01-00-01

CaseID: 11176579

Form Approved: OMB No. 0910-0291, Expires: 8/30/2015
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 (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: INFANT 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)
05/00/2015	05/19/2015

5. Describe Event or Problem

MOTHER SENT AN E-MAIL THAT HER CHILD DEVELOPED BELLADONNA TOXICITY AFTER TAKING 2 TABLETS AND EXHIBITED SYMPTOMS OF WRITHING, ALTERED STATE, CRYING, DILATED PUPILS, CONFUSION, STAGGERED PACE WHEN CRAWLING, UNSTEADY WHEN TRYING TO STAND.

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(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 2 TABS SL 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	#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)

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JUN - 9 20

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
JUN - 8 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.

11176579-01-00-02

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)*: 05/18/2015
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)**: BELLADONNA TOX, WRITHING, ALTERED STATE, CRYING, DILATED PUPILS, CONFUSION, STAGGERING, UNSTEADY
9. **Manufacturer Report Number**: 54973 AE # 1607

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 - 9 2015

JUN - 8 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.

11176579-01-00-03

COMPLAINT #: 2617

DATE OF COMPLAINT: 05/18/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS ITEM CODE: BTET

SIZE: NOT PROVIDED LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS: N/A

CITY: N/A STATE: N/A

COUNTRY: USA ZIP CODE: N/A

PHONE #: NOT PROVIDED

E-MAIL: (b) (6)

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL: MY BABY SHOWED SYMPTOMS OF BELLADONNA TOXICITY AFTER USING TWO OF YOUR TEETHING TABLETS, SHE WAS WRITHING FOR HOURS, IN AN ALTERED STATE, CRYING (WHICH SHE HEVER DOES FOR MORE THAT A FEW SECONDS OR HALF A MINUTE, BUT NOT HOURS), DILATED PUPILS, CONFUSED, STAGGERED PACE WHEN TRYING TO CRAWL AND COULD BARELY HOLD HERSLEF UP WHEN TRYING TO STAND. I AM LIVID AND NOW VERY FRIGHTENED THIS COULD HAVE DONE LASTING DAMAGE TO HER. I EXPECT A RESPONSE IMMEDIATELY AND I WILL PURSUE THIS BY OTHER MEANS AS WELL. NO BABY OR CHILD SHOULD GO THROUGH THIS. EVER. THIS SHOULD NOT BE ON THE MARKET AND THIS COMPANY SHOULD BE BANNED FROM PRODUCING ANYTHING.

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: 05/18/2015

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

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS

JUN - 9 2015

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1607

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/18/2015 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 05-27-15

BY: Eric Bain DATE: 05-21-15

QA / QC DIRECTOR

cc: QA / QC Production
Packaging Shipping / Receiving

JUN - 8 2015

Form # VD1

11176579-01-00-04

NDARD PATHIC
USA SINCE 1903

Serious Adverse Event
SAE-0016-2015

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 forty-two (142) Adverse Events (AE) which also included fifty-one (51) 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

5/21/2015
Date

DSS
JUN - 9 2015

JUN - 8 2015

11176579-01-00-05

Hylands 11176579

SE EVENT DATA FORM

AE #: 1607 **COMPLAINT #:** 2617

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

JUN - 9 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWatt DATE: 05-27-15

BY: Eric Bain DATE: 05-21-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUN - 8 2015

Individual Case Safety Report

Form Approved: OMB No. 0910-0291 Expires: 3/30/2015
See OMB statement on reverse.

11179757-01-00-01

by user-facilities,
butors and manufacturers
)ATORY reporting

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)	4 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)*
00/00/0000	05/21/2015

5. **Describe Event or Problem**

MOTHER POSTED ON (b) (6) THAT SON HAD A FEW SEIZURES WITHIN A 24 HOUR PERIOD AFTER USING THE TABLETS. SEIZURES RESOLVED AFTER TABLETS WERE DISCONTINUED.

(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)

OTC

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	#1
#2	#2

RECEIVED JUN 09 2015 CDR

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)*

(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 JUN 10

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

JUN – 9 2015

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)*: 05/21/2015

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 # ____

9. **Manufacturer Report Number**: 54973 AE # 1609

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

JUN 10 2015

JUN - 9 2015

HOMEOPATHIC
MADE IN THE USA SINCE 1903

CaseID: 11179757

SECTION I: **COMPLAINT**

COMPLAINT #: 2619

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/21/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: N/A

LOT NO.: N/A

REPORTER: (b) (6)

Individual Case Safety Report

11179757-01-00-03

STATE: N/A

ZIP CODE: N/A

PHONE #:

E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (b) (6) AND DID NOT RESPOND TO REQUEST TO CONTACT HYLAND'S: RIGHT AFTER I USED THESE TABLETS MY SON HAD A SEIZURE HE WAS ONLY 4 MONTHS OLD STOPS THEM AND HE WAS FINE DON'T USE THESE WARNING. NOT SHUR WHAT I CAN REALLY SAY ALL I KNOW IS MY SON WAS TEETHING I PICKED UP THE TEETHING TABLETS AND MY SON HAD A FEW SEIZURES OF THE NEXT 24 HRS.

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**: 05/21/2015

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 #: 1609

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/21/2015

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-01-15 DSS

JUN 10 2015

BY: QA / QC DIRECTOR

DATE: 05-29-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

JUN - 9 2015

11179757-01-00-04

NDARD PATHIC USA SINCE 1903

Serious Adverse Event
SAE-0018-2015

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 forty-three (143) Adverse Events (AE) which also included fifty-two (52) 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

5/28/2015
Date

DSS
JUN 10 2015

JUN – 9 2015

11179757-01-00-05

RSE EVENT DATA FORM

AE #: 1609 COMPLAINT #: 2619

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:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 06-01-15

DSS
JUN 10 2015

BY: Erin Bonin DATE: 05-29-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

JUN - 9 2015

Individual Case Safety Report

11179760-01-00-01

CaseID: 11179760

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

OTC

...r user-facilities,
...itors and manufacturers
...TORY 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:	3. Sex	4. Weight
(b) (6)	11 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)*
- ☐ 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)*
05/25/2015	05/27/2015

5. **Describe Event or Problem**

PHARMACIST REPORTS THEY HAVE AN 11 MONTH OLD FEMALE PATIENT THAT IS PRESENTING TO ER WITH BRUISES AND RED SPOTS ON SKIN.

(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	#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

REC

JUN 09 2015

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)*

CDR

(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

JUN 10 2015

Phone #	Email Address
(b) (6)	

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

JUN - 9 2015

11179760-01-00-02

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)* 05/25/2015

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)** BRUISES AND RED SPOTS ON SKIN

9. **Manufacturer Report Number** 54973 AE # 1612

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 10 2015

JUN – 9 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.

HOMEOPATHIC
MADE IN THE USA SINCE 1903

Case [redacted]9760

SECTION I: **COMPLAINT**

COMPLAINT #: 2622

TAKEN BY: (b) (6)

DATE OF COMPLAINT: 05/25/2015

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: N/A

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT: REPORTER IS A PHARMACIST CALLING FROM THE ER DEPT AT (b) (6) N (b) (6) HE REPORTS THEY HAVE AN 11 MONTH OLD FEMALE PATIENT THAT HAS BEEN USING BABY TEETHING TABS. SHE IS PRESENTING TO ER WITH BRUISES AND RED SPOTS ON SKIN. REPORTER WOULD LIKE TO KNOW IF THERE ARE ANY INGREDIENTS IN THE PRODUCT ASSOCIATED WITH HEMOLYTIC ANEMIA OR SOME SORT OF THROMBOCYTOPENIA. REPORTER WOULD NOT PROVIDE ANY FURTHER INFORMATION REGARDING THE CHILD'S SYMPTOMS, HISTORY, OR USE OF THE PRODUCT. HE WILL ASK THE FAMILY TO CALL BACK TO PROVIDE ADDITIONAL 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)

Individual Case Safety Report

DATE REQUESTED PRODUCT BE RETURNED:

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

11179760-01-00-03

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/25/2015

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 #: 1612

DSS

JUN 10 2015

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/25/2015

BY: (b) (6)

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-01-15

BY:

QA / QC DIRECTOR

DATE: 05-29-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

JUN - 9 2015

11179760-01-00-04

NDARD
PATHIC
JSA SINCE 1903

.dverse Event
SAE-0022-2015

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 forty-seven (147) Adverse Events (AE) which also included fifty-six (56) 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

5/28/2015
Date

DSS
JUN 10 2015

JUN - 9 2015

11179760-01-00-05

SE EVENT DATA FORM

AE #: 1612 **COMPLAINT #:** 2622

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

NAME: UNKNOWN

ADDRESS: (b) (6)

CITY: STATE:

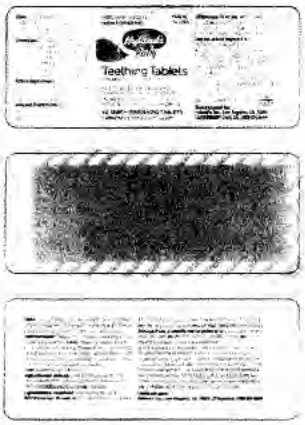
COUNTRY: USA ZIP CODE:

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:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 06-01-15

BY: QA / QC DIRECTOR DATE: 05-29-15

DSS JUN 10 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUN – 9 2015

Individual Case Safety Report

11179773-01-00-01

CaseID: 11179773

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 #

OTC

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)	5 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)*
00/00/0000	05/26/2015

5. **Describe Event or Problem**

CHILD DEVELOPED INFANT BOTULISM AND WAS HOSPITALIZED FOR 3 MONTHS.

(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 HYLAND'S BABY NIGHTTIME TEETHING TABLETS

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

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

#1 TEMP RELIEF TEETHING PAIN

#2 TEMP RELIEF TEETHING PAIN

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, 54973-3197-1

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**

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
JUN 10 2015

Phone #	Email Address

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

JUN - 9 2015

CaseID: 11179773

11179773-01-00-02

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)*: 05/21/2015

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)**: INFANT BOTULISM

9. **Manufacturer Report Number**: 54973 AE # 1611

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
JUN 10 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.

JUN - 9 2015

11179773-01-00-03

:OMPLAINT RECORD

Case 1:19-cv-09773

COMPLAINT #: 2621

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 05/21/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS; HYLAND'S BABY NIGHTTIME TEETHING TABLETS

ITEM CODE: BTET; BTNT----T135

SIZE: UNKNOWN ; 135 TABS

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT: MOTHER POSTED THE FOLLOWING COMMENTS REGARDING PRODUCT AND IT'S NOT CLEAR WHETHER SHE WAS REFERRING TO THE BABY TEETHING TABLETS OR BABY NIGHTTIME TEETHING TABLETS. SHE DID NOT CONTACT HYLAND'S TO PROVIDE MORE INFORMATION. THEY MADE MY DAUGHTER SICK WITH INFANT BOTULISM AT 5 MONTHS OLD. SHE WAS HOSPITALIZED FOR ALMOST 3 MONTHS. I ALMOST LOST HER. I NO LONGER TRUST THIS BRAND.

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**: 05/21/2015

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 #: 1611

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/21/2015

BY: EDYTA FRACKIEWICZ

DSS

JUN 10 2015

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-01-15

BY:

QA / QC DIRECTOR

DATE: 05-29-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

JUN - 9 2015

11179773-01-00-04

NDARD
ATHIC
SA SINCE 1903

Serious Adverse Event
SAE-0021-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) & Hyland's Nighttime Baby Teething Tablets (BTNT) but no lot numbers, 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 forty-seven (147) Adverse Events (AE) which also included fifty-six (56) 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. There have been no other Adverse Events (AE) or Serious Adverse Events reported for the Hyland's Nighttime Baby Teething Tablet lots (BTNT)

Although, the BTET or BTNT lot numbers cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet and Nighttime Baby Teething Tablets 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

5/28/15
Date

DSS
JUN 10 2015

CC-0429-2015
AE-0238-2015

JUN - 9 2015

SE EVENT DATA FORM

AE #: 1611 COMPLAINT #: 2621

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

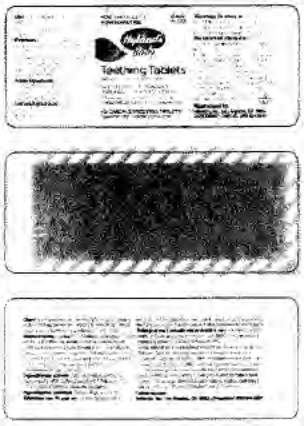
COUNTRY: USA ZIP CODE:

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:

REVIEWED BY MANAGEMENT BY: DATE: 06-01-15

BY: QA / QC DIRECTOR DATE: 05-29-15

DSS JUN 10 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

JUN - 9 2015

11179773-01-00-06

Case ID: 11179773

E EVENT DATA FORM

AE #: 1611 **COMPLAINT #:** 2621

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:

REVIEWED BY MANAGEMENT BY: PWcult DATE: 06-01-15

BY: Gina Bunn DATE: 05-29-15
QA / QC DIRECTOR

DSS
JUN 10 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

JUN – 9 2015

Individual Case Safety Report

CaseID: 11179851

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

11179851-01-00-01

by user-facilities,
butors and manufacturers
)ATORY reporting

Mfr Report # ~~54973-~~

UF/Importer Report #

OTC

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: 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): 05/23/2015

4. Date of This Report (mm/dd/yyyy): 05/26/2015

5. Describe Event or Problem

THE REPORTER STATED THAT CHILD WAS GIVEN A 2 TABLET DOSE AND THEN WAS GIVEN A SECOND 2 TABLET DOSE "A COUPLE OF HOURS LATER" THEN ABOUT (b) (6) AFTER THE SECOND DOSE, THE CHILD BEGAN TO EXHIBIT CONVULSIONS, TURNED BLUE, AND HER EYES WERE ROLLING BACK IN HER HEAD. THE REPORTER STATED THAT THIS "SEIZURE" LASTED FOR ABOUT 30 SECONDS. FOLLOWING THIS EPISODE, THE REPORTER TOOK THE CHILD'S TEMPERATURE AND FOUND THAT SHE HAD A FEVER OF 103 DEGREES FAHRENHEIT. SOME TIME LATER, THE CHILD EXPERIENCED ANOTHER EPISODE SIMILAR TO THE FIRST, THAT LASTED FOR ABOUT ONE MINUTE. CHILD TAKEN TO THE ER. DOCTORS IN THE EMERGENCY DEPARTMENT WERE "NOT SURE YET" IF THESE EPISODES WERE SEIZURES. F/U 5/24/15: DIAGNOSED AS FEBRILE SEIZURES POSSIBLY DUE TO SPIKE IN TEMPERATURE CAUSED BY BABY TEETHING TABLETS.

(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.)

TEMPERATURE OF 103 DEGREES FAHRENHEIT FOLLOWING 1ST SEIZURE. F/U 05/24/15: FEVER HAS NOT EXCEEDED 101 DEGREES FAHRENHEIT.

(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 TABS EVERY TWO HRS X2
#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

RECEIVED
JUN 09 2015

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

9. NDC# or Unique ID
54973-3141-1

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

CDR

(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)

DSS
JUN 10 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

Phone # (b) (6)

Email Address

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

3. Occupation: NA

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

JUN - 9 2015

11179851-01-00-02

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)*
05/23/2015

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, FEVER

9. **Manufacturer Report Number**
54973 AE # 1610

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 10 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."

JUN - 9 2015

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Case ID: 11179851

SECTION I: **COMPLAINT**

COMPLAINT #: 2620

TAKEN BY: LILIANA GLUBISZ

DATE OF COMPLAINT: 05/23/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: T6

LOT NO.: 123037

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT: THE REPORTER'S 1-YEAR-OLD DAUGHTER WAS GIVEN 4 "BABY TEETHING TABLETS" TODAY FROM A SAMPLE PACKET. THE REPORTER STATED THAT SHE WAS GIVEN A 2 TABLET DOSE AND THEN WAS GIVEN A SECOND 2 TABLET DOSE "A COUPLE OF HOURS LATER." THE REPORTER STATED THAT ABOUT (b) (6) AFTER THE SECOND DOSE, THE CHILD BEGAN TO EXHIBIT CONVULSIONS, TURNED BLUE, AND HER EYES WERE ROLLING BACK IN HER HEAD. THE REPORTER STATED THAT THIS "SEIZURE" LASTED FOR ABOUT 30 SECONDS. FOLLOWING THIS EPISODE, THE REPORTER TOOK THE CHILD'S TEMPERATURE AND FOUND THAT SHE HAD A FEVER OF 103 DEGREES FAHRENHEIT. SOME TIME LATER, THE CHILD EXPERIENCED ANOTHER EPISODE SIMILAR TO THE FIRST, THOUGH THIS SECOND EPISODE LASTED FOR ABOUT ONE MINUTE. AT THE TIME OF THE CALL, THE REPORTER HAD BEEN IN THE EMERGENCY DEPARTMENT FOR ABOUT 90 MINUTES. HE STATED THAT THE DOCTORS IN THE EMERGENCY DEPARTMENT WERE NOT "NOT SURE YET" IF THESE EPISODES WERE SEIZURES. (SEE ATTACHED)

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

11179851-01-00-03

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: 05/23/2015

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: LILIANA GLUBISZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1610

ADVERSE EVENT SERIOUS: (Y) / N

DSS

ADVERSE EVENT REPORTED ON: 05/23/2015 BY: LILIANA GLUBISZ

JUN 10 2015

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-01-15

BY: Eric Baum
QA / QC DIRECTOR

DATE: 05-29-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

JUN – 9 2015

Form 0001

REPORTER: (b) (6) COMPLAINT # 1620

THE REPORTER STATED THAT THE CHILD HAS NEVER EXPERIENCED ANYTHING LIKE THIS BEFORE. HE STATED THAT SHE HAS NO KNOWN ALLERGIES.

THE REPORTER ASKED WHAT THE HALF LIFE WAS FOR BELLADONNA. HE STATED THAT HE WANTED TO KNOW THE MANUFACTURING DATE OF HIS LOT NUMBER TO MAKE SURE THAT THE TABLETS WERE NOT RECALLED. WHEN ASKED, HE STATED THAT THE CALCAREA CARBONICA ACTIVE INGREDIENT WAS LISTED AS A 6X POTENCY. HE STATED THAT IT WOULD BE OKAY TO CONTACT HIM TOMORROW.

F/U 05/24/2015 WITH THE REPORTER'S WIFE: SHE STATED THAT THE CHILD IS IMPROVING TODAY AND THAT HER FEVER HAS NOT GONE HIGHER THAN 101 DEGREES FAHRENHEIT TODAY. SHE STATED THAT THE ER DOCTOR DID NOT RECOMMEND TRANSFERRING THE CHILD TO A CHILDREN'S HOSPITAL AS THE CHILDREN'S FACILITY WAS LOCATED AN HOUR AWAY AND THE DOCTOR FELT THAT THE SITUATION WAS NO LONGER EMERGENT AS THE SEIZURES HAD ALREADY OCCURRED. SHE STATED THAT THE CHILD WAS NOT ADMITTED TO THE HOSPITAL. SHE STATED THAT THE CHILD'S FEVER YESTERDAY WAS ASSOCIATED WITH TEETHING. SHE STATED THAT THERE WAS SPECULATION BY THE ER DOCTOR THAT THE "BABY TEETHING TABLETS" COULD HAVE CAUSED THE LOW-GRADE FEVER TO SPIKE, WHICH MAY HAVE PROMPTED THE SEIZURES. SHE STATED THAT THE ER DOCTOR VERIFIED THAT THE CHILD EXPERIENCED TWO SEIZURES AND STATED THAT THEY COULD BE FEBRILE SEIZURES. I RECOMMENDED THAT THEY DISCONTINUE USING THE "BABY TEETHING TABLETS" AT THIS TIME AND THAT THEY CONTACT ME OR THE COMPANY IF THEY HAVE ANY OTHER QUESTIONS. I ALSO OFFERRED HER A REFUND, WHICH SHE SAID WOULD NOT BE NECESSARY.

11179851-01-00-05

VDARD
ATHIC
SA SINCE 1903

dverse Event
SAE-0019-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET) packets, lot # 123037, 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 # 123037 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 # 123037. The Baby Teething bulk lot # 123037 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(b)(4) ppm.

Retention Samples:

Retention samples of packets are not kept therefore an inspection of the packet retain 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 complaints have been received for Hyland's Baby Teething Tablets packets lot # 123037. A review of complaints associated with lots manufactured using the same bulk (123037) was conducted and four complaints (CC-0654-2014, CC-0847-2014, CC-0814-2014 & CC-0045-2015) were found. The complaints were reviewed but they do not appear to be 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 # 123037.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

5/28/2015
Date

DSS
JUN 10 2015

JUN - 9 2015

11179851-01-00-06

RSE EVENT DATA FORM

AE #: 1610 **COMPLAINT #:** 2620

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: 06-01-15

BY: QA / QC DIRECTOR DATE: 05-29-15

DSS
JUN 10 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUN – 9 2015

11188555-01-00-01

CaseID: 11188555

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

by user-facilities,
butors and manufacturers
)ATORY 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: 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)
- ☐ 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): 05/14/2015

4. Date of This Report (mm/dd/yyyy): 05/28/2015

5. Describe Event or Problem:
CHILD EXPERIENCING SEIZURES WHICH STARTED 2 WEEKS AGO AND HAPPEN EVERY OTHER DAY. DISCONTINUED BABY TEETHING TABLETS 5/27/15 PM. CHILD HAD A SEIZURE 5/28/15 AFTER HE DISCONTINUED THE BABY TEETHING TABLETS.

(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.)
FATHER HAS SEIZURE DISORDER AND ON MEDICATION. CHILD HAS BEEN HAVING FEVERS NOT EXCEEDING 101 DEGREES FAHR.

(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 TAB PO BID X 1 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 A36714
#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 #

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)

Phone #
(b) (6)

Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

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

DSS
JUN 12 2015

JUN 11 2015

Received
JUN 11 2015
CDR

CaseID: 11188555

11188555-01-00-02

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)*: 05/28/2015

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 # 1614

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
JUN 12 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:

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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov
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JUN 11 2015

11188555-01-00-03

COMPLAINT #: 2624

DATE OF COMPLAINT: 05/28/2015

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET---T40

SIZE: 40 TABS

LOT NO.: A36714

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT: GIVES 1 TAB BID X 1 MONTH. SEIZURES STARTED 2 WEEKS AGO AND HAPPEN EVERY OTHER DAY. STOPPED TEETHING TABLETS YESTERDAY. CHILD HAD A SEIZURE TODAY EVEN AFTER HE STOPPED THE TEETHING TABLETS. FATHER HAS SEIZURE DISORDER AND IS ON MEDICATION. FATHER CANNOT DESCRIBE SEIZURES BECAUSE HE IS NOT HOME WHEN THEY HAPPEN AND HAS NOT SEEN ONE AND ONLY HIS WIFE HAS SEEN THEM.

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:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/28/2015

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 #: 1614

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 05/28/2015 BY: EDYTA FRACKIEWICZ

DSS JUN 12 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 06-03-15

BY: QA / QC DIRECTOR DATE: 06-03-15

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

JUN 11 2015

INDARD
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Adverse Event
SAE-0023-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A36714, 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 # A36714 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 # A36714. The Baby Teething bulk lot # 123037 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-0654-2014) has been received for Hyland's Baby Teething Tablets lot # A36714. A search of complaints of products manufactured using the same bulk lot (123037) was also conducted and revealed four complaints (CC-0847-2014, CC-0814-2014, CC-0045-2015 & CC-0422-2015). The complaints were reviewed and although CC-0422-2015 does indicate a similar reaction as indicated in this instance they do not appear to be related are both isolated incidents. 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 # A36714.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/2/2015
Date

DSS
JUN 12 2015

JUN 11 2015

11188555-01-00-05

88555

SE EVENT DATA FORM

AE #: 1614 **COMPLAINT #:** 2624

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

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

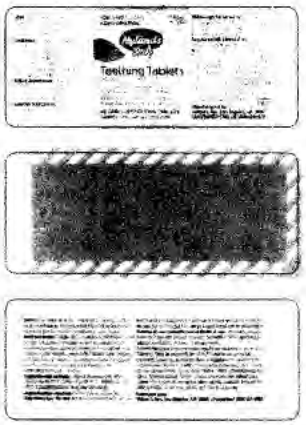
COUNTRY: USA ZIP CODE:

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

JUN 12 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Wolff DATE: 06-03-15

BY: Eric Bain DATE: 06-03-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUN 11 2015

Individual Case Safety Report

11254142-01-00-01

Case ID: 11254142

essional Report

CDER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

reporting of
ct problems and
product use errors

1/2

FDA USE ONLY
Triage unit sequence # 604369

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
BOY In confidence	15 Months (b) (6)	☐ Female ☑ Male	25.7 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)*
06/30/2015	07/07/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) 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 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: Hyland's 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 month
#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 JUL – 8 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
Name: (b) (6)
Address:
City: State: ZIP:

US DSS
JUL 8 2015

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

11254142-01-00-02

likely brief seizure

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)*

healthy infant with no other predisposing factors

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

none

Individual Case Safety Report

CaseID: 11258215

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

11258215-01-00-01

y user-facilities,
ıtors and manufacturers
ATORY reporting

Page 1 of 6

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

OTC

FORM FDA 3500A (2/15)

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	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)*
06/18/2015	06/18/2015

5. **Describe Event or Problem**

MOTHER REPORTS ON (b) (6) THAT SHE GAVE TABLETS TO HER BABY AND BABY HAD SEIZURES THAT WERE ATTRIBUTED TO FEVER.

(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 HYLAND'S TEETHING TABLETS

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

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JUL 08 2015
CDR

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

9. **NDC# or Unique ID**

54973-3127-3; 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)

DSS

E. INITIAL REPORTER

JUL 9 2015

1. **Name and Address**

(b) (6)

Phone #	Email Address

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

JUL - 8 2015

11258215-01-00-02

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)*: 06/18/2015

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 # 1616

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 9 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."

JUL - 8 2015

HOMEOPATHIC
MADE IN THE USA SINCE 1903

Case [illegible]8215

SECTION I: **COMPLAINT**

COMPLAINT #: 2626

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/18/2015

PRODUCT: BABY TEETHING TABLETS/ TEETHING TABLETS

ITEM CODE: BTET / TEET

SIZE: N/A

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS: N/A

Individual Case Safety Report

11258215-01-00-03

STATE: N/A

ZIP CODE: N/A

E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING COMMENT ON (b) (6) OF HYLAND'S BABY TEETHING TABLETS: I WISH I WOULD HAVE KNOWN ABOUT THE RECALL WHEN IT ACTUALLY HAPPENED, SINCE I GAVE THESE TO MY BABY AND SHE HAD SEIZURES THAT WE ATTRIBUTED TO FEVER. (b) (6)

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:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 06/18/2015

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

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: EDYTA FRACKIEWICZ

DATE: 06/18/2015

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1616

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: BY:

DSS

JUL 9 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: RWdH DATE: 06-29-15

BY: Eric Bain QA / QC DIRECTOR DATE: 06-26-15

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

Form # VD1

JUL - 8 2015

11258215-01-00-04

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Iverse Event
SAE-0025-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) & Hyland's Teething Tablets (TEET) but no lot numbers, 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 fifty-two (152) Adverse Events (AE) which also included fifty-seven (57) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). There were ten (10) Adverse Events (AE) and nine (9) of them as elevated to an SAE for they 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.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething 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

6/26/2015
Date

DSS
JUL 9 2015

JUL - 8 2015

11258215-01-00-05

Case 11258215

EVENT DATA FORM

AE #: 1616 **COMPLAINT #:** 2626

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: 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 9 201

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 06-29-15

BY: Eric Bain DATE: 06-26-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUL - 8 2015

FORM SAE01

11258215-01-00-06

58215

VENT DATA FORM

AE #: 1616 **COMPLAINT #:** 2626

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

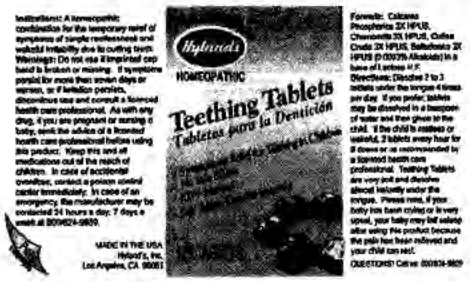
COUNTRY: ZIP CODE:

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 9 2

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

BY: Eric Bain DATE: 06-26-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

JUL - 8 2015

Individual Case Safety Report

11275465-01-00-01

CaseID: 11275465

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

...r user-facilities,
...itors and manufacturers
...TORY reporting

FORM FDA 3500A (2/13)

Mfr Report # 54973

UF/Importer Report #

OTC

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	9 Months 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)*
- ☐ 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)*
06/12/2015	06/23/2015

5. Describe Event or Problem

CHILD HAD HIGH FEVER OF 103-104 AND DEVELOPED SEIZURES (DESCRIBED AS JERKING, EYES ROLLING BACK, UNABLE TO CRY OR MAKE SOUNDS) 2 HOURS AFTER TAKING ONE DOSE OF BABY TEETHING TABLETS. HE ALSO HAD SEIZURES THE NEXT NIGHT, AFTER TABLETS WERE STOPPED.
CHILD WAS PRESCRIBED ANTIBIOTICS, MOTRIN & TYLENOL BY DOCTOR.

Received
JUL 14 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.)*

TEETHING. MOTRIN AND TYLENOL WERE USED AS NEEDED.

(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, ONCE, ORAL	#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 B21514	#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
JUL 15 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)
(b) (6) USA

JUL 14 2015

Phone #	Email Address
(b) (6)	

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

PLEASE TYPE OR USE BLACK INK

CaseID: 11275465

11275465-01-00-02

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)*: 06/22/2015

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 # 1618

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 15 2015

JUL 14 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

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STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1993

CUSTOMER COMPLAINT RECORD

Ca[illegible]/5465

SECTION I: **COMPLAINT**

COMPLAINT #: 2628

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 06/22/2015

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET—T40

SIZE: 40 TABS

LOT NO.: B21514

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT: 9 MONTH OLD HAD SEIZURES ON (b) (6) HE HAD A FEVER OF 104, AND WAS GIVEN ONE DOSE ONCE OF 2 TABLETS OF BABY TEETHING TABLETS AT 6 PM. AT 8 PM HE EXPERIENCED 'BACK TO BACK SEIZURES', JERKING AND EYES ROLLING BACK, UNABLE TO CRY OR MAKE SOUNDS. MOTHER TOOK HIM TO THE HOSPITAL AND WHILE DRIVING THERE HE HAD A 5 MINUTE SEIZURE IN THE CAR. AT THE HOSPITAL, SHE DOES NOT REMEMBER IF THEY DID ANY TESTS, BUT HE DID SEE 2 DOCTORS WHO DIAGNOSED IT AS FEBRILE SEIZURES AND PRESCRIBED ANTIBIOTICS, MOTRIN AND TYLENOL. THE NEXT DAY, (b) (6) HE AGAIN DEVELOPED SEIZURES IN THE EVENING, HAD A FEVER OF 103-104, AND MOTHER TOOK HIM TO THE HOSPITAL WHERE THEY RECOMMENDED THE SAME TREATMENT: ANTIBIOTICS, MOTRIN AND TYLENOL. THEY SAID IF HE HAS SEIZURES AGAIN, TO TAKE HIM TO THE CHILDREN'S HOSPITAL.
AS OF YET, THE CHILD HAS NO TEETH, BUT HAS SYMPTOMS OF TEETHING: RUBBING HIS GUMS AND INCREASED SALIVATION.
MOTHER HAD GIVEN HIM MOTRIN AND TYLENOL PRIOR TO THIS EVENT WITH NO 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: 06/22/2015

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

SECTION III: **CORRECTIVE ACTION:**

Individual Case Safety Report

11275465-01-00-03

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: JS JUL 15 2015

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1618

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/22/2015 BY: TUTTI GOULD JUL 14 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 07-01-15

BY: Eric Bain QA / QC DIRECTOR DATE: 07-01-15

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

Form # VD1

11275465-01-00-04

VDARD ATHIC SA SINCE 1903

verse Event

SAE-0027-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # B21514, 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 # B21514 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 # B21514. The Baby Teething bulk lot # 123902 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-0490-2015) has been received for Hyland's Baby Teething Tablets lot # B21514. 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 # B21514.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/30/2015
Date

DSS
JUL 15 2015

JUL 14 2015

Individual Case Safety Report

11275465-01-00-05

Case 11275465

E EVENT DATA FORM

AE #: 1618 COMPLAINT #: 2628

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

NAME: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

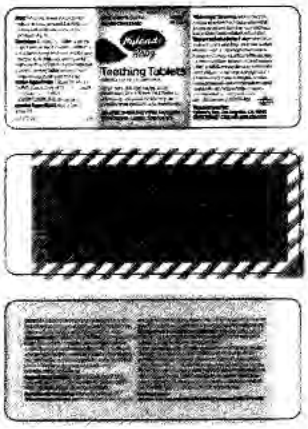
COUNTRY: USA ZIP CODE:

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 15 2015

JUL 14 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 07-01-15

BY: DATE: 07-01-15

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Individual Case Safety Report

11275478-01-00-01

CaseID: 11275478

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

by user-facilities,
outors and manufacturers
ATORY reporting

Mfr Report # 54973

UF/Importer Report # OTC

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

3. Date of Event (mm/dd/yyyy): 06/16/2015

4. Date of This Report (mm/dd/yyyy): 06/26/2015

5. Describe Event or Problem

ABOUT 10 MINUTES AFTER A DOSE OF BABY TEETHING TABLETS HIS WHOLE BODY WAS TWITCHING (ARMS AND LEGS) WHICH LASTED ABOUT 15 MINUTES. HAPPENED A SECOND TIME THAT SAME DAY AFTER MOTHER GAVE THE TABLETS AGAIN. MOTHER STATED "I WOULDN'T CALL IT A SEIZURE". MOTHER STATES THAT THE TWITCHING WAS NOT AS DRAMATIC OR VIOLENT AS A SEIZURE WOULD BE. SHE STOPPED USING THE TABLETS AND CHILD HAS NOT HAD A TWITCHING EPISODE SINCE.

(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.)

IMMUNIZATIONS JUNE 10

(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 N/A

2. Dose, Frequency & Route Used
- #1 3 TABS BID PRN TEETHING
- #2 N/A

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 N/A

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

Received JUL 15 2015

6. Lot #
- #1 A29815
- #2 N/A

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 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: ☐ 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 15 2015 USA 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.

CaseID: 11275478

11275478-01-00-02

FDA USE ONLY

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)*: 06/26/2015
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)**: POSSIBLE SEIZURES
9. **Manufacturer Report Number**: 54973 AE # 1619

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 16 2015

DSS JUL 15 2015 JUL 14 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.

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

SECTION I: COMPLAINT

COMPLAINT #: 2629

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/26/2015

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABS

LOT NO.: A29815

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT: MOTHER HAS BEEN GIVING CHILD 3 TABS BID ON AND OFF SPORADICALLY. GAVE HIM 3 TABS 1.5 WEEKS AGO. ABOUT 10 MINUTES AFTER THIS DOSE HIS WHOLE BODY WAS TWITCHING (ARMS AND LEGS) WHICH LASTED ABOUT 15 MINUTES. HAPPENED A SECOND TIME THAT SAME DAY AFTER SHE GAVE THE TABLETS AGAIN. MOTHER STATED "I WOULDN'T CALL IT A SEIZURE". MOTHER STATES THAT THE TWITCHING WAS NOT AS DRAMATIC OR VIOLENT AS A SEIZURE WOULD BE. SHE STOPPED USING THE TABLETS AND HE HAS NOT HAD A TWITCHING EPISODE SINCE. HAD AN IMMUNIZATION ON JUNE 10TH 4-5 DAYS BEFORE GETTING THE TWITCHING. 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: 06/26/2015

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

SECTION III: CORRECTIVE ACTION:

Individual Case Safety Report

11275478-01-00-03

DSS

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: JUL 1 6 2015

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1619

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/26/2015 BY: EDYTA FRACKIEWICZ

JUL 1 4 2015

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 07-07-15

BY:

QA / QC DIRECTOR

DATE: 07-07-15 DSS

JUL 15 2015

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

11275478-01-00-04

NDARD PATHIC USA SINCE 1903

dverse Event
SAE-0028-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A29815, 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 # A29815associated 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 # A29815. The Baby Teething bulk lot # 125264 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-0525-2015) has been received for Hyland's Baby Teething Tablets lot # A29815. 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 # A29815.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

7/6/2015
Date

JUL 14 2015

DSS

JUL 15 2015

11275478-01-00-05

11275478

SE EVENT DATA FORM

AE #: 1619 **COMPLAINT #:** 2629

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

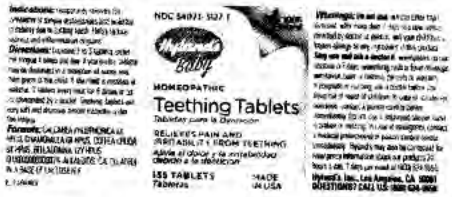
COUNTRY: ZIP CODE:

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: JUL 15 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 07-07-15

BY: QA / QC DIRECTOR DATE: 07-07-15

JUL 14 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

11279245-01-00-01

Form Approved: OMB No. 0910-0291 Expires: 6/30/2015
See OMB statement on reverse.

CaseID: 11279245

user-facilities,
ors and manufacturers
ORY reporting

1 of 5

Mfr Report # 54973

UF/Importer Report #

OTC

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: 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)*: 07/01/2015

4. Date of This Report *(mm/dd/yyyy)*: 07/01/2015

5. Describe Event or Problem

(b) (6) CUSTOMER POSTED ON THAT HER BABY WAS BORN NORMAL UNTIL SHE GAVE HER THE HYLAND'S BABY TEETHING TABLETS. CHILD HAD A BLEED IN THE BRAIN AND SEIZURES. CHILD NOW HAS DEVELOPMENTAL DELAY WITH DELAYS IN SPEECH, WALKING, PLAYING.

Received
JUL 15 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.)*

(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
#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
54973-3127-3

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)*

JUL 16 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 JUL 15 2015

Phone #

Email Address

2. Health Professional?
☐ Yes ☑ No

3. Occupation
NA

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

CaseID: 11279245

11279245-01-00-02

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): 07/01/2015
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): BRAIN BLEED, SEIZURES, DEVELOPMENTAL DELAY
9. Manufacturer Report Number: 54973 AE # 1620

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 16 2015

JUL 15 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

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Please DO NOT RETURN this form to the above PRA Staff email address.

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Case Planet 9245

SECTION I: COMPLAINT

COMPLAINT #: 2630

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 07/01/2015

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: N/A

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (b) (6) **** U HYLANDS,MY BABY WAS BORN NORMAL UNTIL I GAVE HER UR DAM TEETHING TABLETS, THEN SHE ENDED UP WITH A BLEED IN HER BRAIN AND SEIZURES, I HATE UR COMPANY, U TOOK MY BADDIES LIFE FROM HER, SHE WILL NEVER B NORMAL OR DO NORMAL THINGS,SHE IS FOREVER DELAYED, WITH SPEECH, WALKING, PLAYING. I HATE, HATE, HATE U FOR THIS! !!!!

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

11279245-01-00-03

DATE REQUESTED PRODUCT BE RETURNED:

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

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 07/01/2015

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

SECTION III: CORRECTIVE ACTION:

DSS
JUL 16 2015

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1620

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 07/01/2015

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 07-09-15

BY:
QA / QC DIRECTOR

DATE: 07-09-15

JUL 15 2015

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

11279245-01-00-04

NDARD PATHIC USA SINCE 1903

Adverse Event

CAE-0029-2015

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-two (132) Adverse Events (AE) which also included forty-nine (49) 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 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

7/8/15
Date

DSS
JUL 16 2015

JUL 15 2015

SE EVENT DATA FORM

AE #: 1620 **COMPLAINT #:** 2630

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

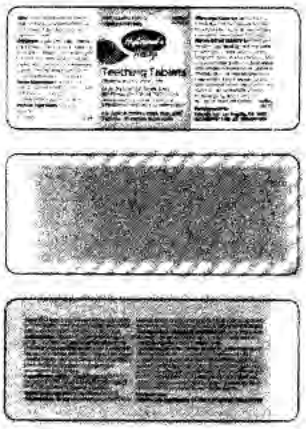
COUNTRY: USA ZIP CODE:

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

JUL 16 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 07-09-15

BY: QA / QC DIRECTOR DATE: 07-09-15

JUL 15 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 11301071

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

11301071-01-00-01

ser-facilities,
rs and manufacturers
DRY reporting

Mfr Report #	54973
UF/Importer Report #	

OTC 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:	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)*
- ☐ 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)*
06/30 - 07/01/15	07/08/15

5. Describe Event or Problem

CHILD HAD A SEIZURE ON (b) (6) DESCRIBED AS TREMBLING, EYES ROLLING BACK, CHOKING ON TONGUE. CHILD HAD A TOTAL OF 5 SEIZURES FROM (b) (6) THE 5TH SEIZURE OCCURRED A FEW MINUTES AFTER A DOSE OF BABY TEETHING TABLETS. LAST DOSE OF BABY TEETHING TABLETS WAS ON (b) (6) AND SINCE THEN CHILD HAS NOT HAD ANOTHER SEIZURE. DOCTOR DIAGNOSED SEIZURES AS FEBRILE INITIALLY BUT THE CHILD HAD NO FEVER SO THEY CHANGED THE DIAGNOSIS TO SEIZURES CAUSED BY BABY TEETHING TABLETS. CHILD WAS HOSPITALIZED FOR 1.5 DAYS FOR OBSERVATION. CT SCAN AND EEG SCHEDULED 8/12.

(Continue on page 3)

Received
JUL 22 2015
CDR

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 N/A

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

4. Diagnosis for Use *(Indication)*
#1 TEMP RELIEF TEETHING PAIN
#2 N/A

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 N/A	#1
#2 N/A	#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)*

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 23 2015

Phone #	Email Address
(b) (5)	

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

JUL 22 2015

11301071-01-00-02

FDA USE ONLY

1. Check One: ☐ User Facility ☐ Importer

2. Of/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)*: 07/07/15

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 # 1621

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 23 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.

JUL 22 2015

HOMEOPATHIC
MADE IN THE USA SINCE 1903

Case [redacted]301071

SECTION I: **COMPLAINT**

COMPLAINT #: 2631

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 07/07/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET—T135

SIZE: 135 TABS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT:

MOTHER REPORTS THAT CHILD HAS HAD 5 SEIZURES THAT DOCTORS HAVE ATTRIBUTED TO HYLAND'S BABY TEETHING TABLETS. THE FIRST SEIZURE WAS ON (b) (6) AND WAS DESCRIBED AS TREMBLING, EYES ROLLING BACK, CHOKING ON TONGUE. CHILD HAD A TOTAL OF 5 SEIZURES FROM (b) (6) THE 5TH SEIZURE OCCURRED A FEW MINUTES AFTER A DOSE OF BABY TEETHING TABLETS. LAST DOSE OF BABY TEETHING TABLETS WAS ON (b) (6) AND SINCE THEN CHILD HAS NOT HAD ANOTHER SEIZURE. DOCTORS AT FIRST DIAGNOSED SEIZURES AS FEBRILE BUT THE CHILD HAD NO FEVER SO THEY CHANGED THE DIAGNOSIS TO SEIZURES CAUSED BY BABY TEETHING TABLETS. CHILD WAS HOSPITALIZED FOR 1.5 DAYS FOR OBSERVATION. HAS A CT SCAN AND EEG SCHEDULED AUGUST 12TH. NO VACCINATIONS RECENTLY, NO HISTORY OF HEAD INJURY, AND NO FAMILY HISTORY OF 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: 07/07/2015

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 #: 1621

DSS

JUL 23 2015

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 07/07/2015

BY: EDYTA FRACKIEWICZ

SECTION V:

Individual Case Safety Report

DATE: 07-10-15

JUL 22 2015

DATE: 07-10-15

11301071-01-00-03

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

IDARD
ATHIC
IA SINCE 1903

verse Event
SAE-0030-2015

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-four (134) Adverse Events (AE) which also included fifty (50) 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 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

7/9/2015
Date

DSS
JUL 23 2015

JUL 22 2015

11301071-01-00-05

Hyland's 301071

EVENT DATA FORM

AE #: 1621 **COMPLAINT #:** 2631

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

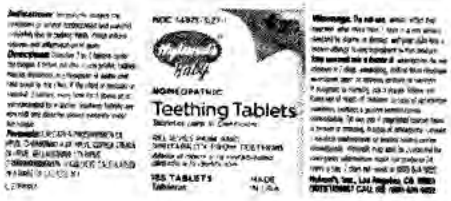
COUNTRY: ZIP CODE:

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

JUL 23 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

JUL 22 2015

REVIEWED BY MANAGEMENT BY: DATE: 07-10-15

BY: DATE: 07-10-15

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE **FORM SAE01**

CaseID: 11364562

11364562-01-00-01

umer Report CDER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

RY reporting of
duct problems and
product use errors

FDA USE ONLY
Triage unit sequence # 6094b9

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	16 Months (b) (6)	☐ Female ☑ Male	29 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)*
08/09/2015	08/09/2015

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: Hyland's Teething Tablets
Strength: Hyland's Teething Tablets
Manufacturer: Manufactured for Hyland's inc.,

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 to 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 03/06/2015 - 05/31/2015
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 My son was teething . Gums were in 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
#1 800 624 9659	#1 06/30/2016	54973-3127-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

AUG 10 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)*

See additional page(s) for complete text.

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

1. Name and Address
(b) (5)

DSS
AUG 10 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

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.

11364562-01-00-02

My name is (b) (6) I have a now 17month old son by the name of (b) (6) Well I'm here to tell you my story . After my son 1st birthday (b) (6) he started growing his teeth . He was teething and his gums were in pain , so I went to Rite-Aid and I purchased Hyland's Teething Tablets . I started giving them to my son and As Needed for a few months . As of (b) (6) (b) (6) my son had a seizure and I called the paramedics and they rushed him to the hospital . They sent us home and on (b) (6) he had 2 more seizure and he was rushed to the hospital once again . They gave him a CatScan and 1 hour EEG and A MRI . He was also admitted I have all the proof and papers and I also have the same bottle of Hyland's Teething Tablets that I was giving my son for his teething . Today I searched on Google what can cause seizure in toddlers and it came up that Hyland's Teething Tablets Causes Seizure I was so shocked to see that the same teething tablets I was giving my son causes seizures and I Immediately Looked into what I need to do to get help please contact me as soon as possible for further information . Thank you ! My Number Is (b) (6) and my email is (b) (6)

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

(b) (6) he was tested for COMPREHENSIVE METABOLIC PANEL , URINALYSIS , XR CHEST 1 VW PORTABLE , DRUG SCREEN/TOX , CBC COMPONENT , CLINITEST . As of (b) (6) He Was Admitted As of (b) (6) He Had An CatScan As of (b) (6) He Had An EEG As of (b) (6) He Had an MRI

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:

Allergies:

Important Information:

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

RX Meds: LEVETIRACETAM KEPPRA

OTC Meds:

Individual Case Safety Report

Form Approved: OMB No. 0910-0291 Expires: 6/30/2015
See OMB Statement on reverse.

CaseID: 1374329

11374329-01-00-01

y user-facilities,
itors and manufacturers
ATORY reporting

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) 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)*
07/28/2015	07/31/2015

5. Describe Event or Problem

CHILD EXPERIENCED SEIZURE LIKE ACTIVITY WITH POSSIBLE HOSPITALIZATION.

Received
AUG 11 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.)*

(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	#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)*

(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.

11374329-01-00-02

☐ 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)*
07/28/2015

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 LIKE ACTIVITY

9. Manufacturer Report Number
54973 AE # 1623

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**

HOMEOPATHIC
MADE IN THE USA SINCE 1903

Case [illegible]4329

SECTION I: **COMPLAINT**

COMPLAINT #: 2633

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 07/28/2015

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: NOT PROVIDED

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

Individual Case Safety Report

11374329-01-00-03

G ON BABY TEETHING TABLETS FACEBOOK PAGE. WAS PROVIDED WITH 2
OTE: 1) YOUR TABLETS CAUSED SEIZURE LIKE ACTIVITY IN OUR
LL STOP MAKING THESE DANGEROUS PILLS. MY BABY HAS BEEN
CONVERSATION OVER THE PHONE WITH MY KIDS AROUND. IS THERE
H. IS THERE ANOTHER EMAIL?

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**: 07/28/2015

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

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: EDYTA FRACKIEWICZ

DATE: 07/28/2015

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1623

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON:

BY:

SECTION V:

REVIEWED BY MANAGEMENT BY: R Wall

DATE: 08-06-15

BY: Gina Bain
QA / QC DIRECTOR

DATE: 08-05-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

INDARD
OPATHIC
E USA SINCE 1903

Adverse Event
:-0032-2015

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 twenty-nine (129) Adverse Events (AE) which also included fifty-three (53) 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 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

8/3/2015
Date

11374329-01-00-05

SE EVENT DATA FORM

AE #: 1623 **COMPLAINT #:** 2633

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

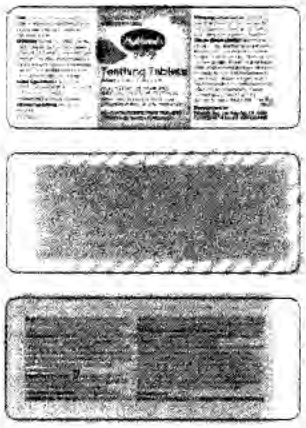
COUNTRY: USA ZIP CODE:

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:

REVIEWED BY MANAGEMENT BY: R Wadt DATE: 08-06-15

BY: Eric Baun DATE: 08-05-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 11395428

11395428-01-00-01

er Report CDER

reporting of
uct 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 # 610758

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	5.5 Months (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)* ☐ 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)*
08/14/2015	08/15/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) 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 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: teething tablets
Strength: hyland's teething tablets
Manufacturer: hyland's

#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 one dose
#2

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

3. Manufacturer Name, City and State

CTU
AUG 17 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
AUG 17 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

11395428-01-00-02

I gave my 5.5 month old son 2 hyland's teething tablets (as directions state) and 20 minutes or so he began throwing up (not baby spitting up, actually vomitting)

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)*

Race: White

Medical Conditions: None

Allergies: None

Important Information: Healthy normal infant boy

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

RX Meds: None

OTC Meds: None at the time, Tylenol infant liquid occasionally

CaseID: 11415807

11415807-01-00-01

er Report CDER

reporting of
t 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 #
611654

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	16 lb or ____ kg

2. Dose or Amount	Frequency	Route
#1 2 pills	At bedtime	Taken by mouth
#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. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
08/13/2015	08/21/2015

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: Nighttime Teething Tablets
Strength:
Manufacturer: Hyland's Baby

#2 Name:
Strength:
Manufacturer:

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 08/10/2015 – 08/15/2015	#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 pain, fussiness, and sleeplessness	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 B31914	#1	54973-3197-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name CTU

3. Manufacturer Name, City and State AUG 24 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)

See additional page(s) for complete text.

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

DSS
G 24 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

11415807-01-00-02

We used Hyland's nighttime teething tablets on my 7 month old daughter starting 8/9/2015. She was given 2 tablets each following night before bedtime. That was the only time of day we gave her any pills. On 8/11/15, I noticed her have an episode which lasted approximately 5 minutes where she was repeatedly tilting her head to the right (ear to shoulder) and it appeared involuntary. This happened 4 other times throughout that day, but the morning episode went on for the longest amount of time. I got a video of her having one of her episodes that night. The following day, 8/12/15, she had 5 episodes throughout the day increasing in duration and her head tilts were getting jerkier and making her torso tilt towards that side. I have a video from that day midday. We saw her pediatrician 8/12/15 to show her the video and see if she had any idea what could be causing it. We didn't think to mention the teething tablets since they were homeopathic and had no warning labels about these adverse effects. On (b) (6) (b) (6) my daughter got much worse and was having torso and head spasms. I have a video of her having an episode in her highchair where her head and torso collapsed onto the tray and bobbed there. I drove her to Children's Hospital in (b) (6) 2 hours away. The doctors did a CT scan, found nothing wrong, and they admitted her to the neurology wing of the hospital. The next morning (b) (6) they ran an MRI which came back normal and did an EEG that afternoon. The neurologist filmed my video from (b) (6) because he said he had never seen anything like this. They discharged her after saying that her symptoms and spasms weren't lining up with any condition 100%. This whole time I hadn't given her any teething tablets because I had forgotten to pack them. She had very few episodes in the hospital. When we arrived home on (b) (6) I gave her a dose of 2 tablets that night before bed and the next morning she had an episode ten minutes after waking and several more throughout the day. I haven't given her any teething tablets since then and every day she has had less episodes. 8/20/15 and 8/21/15 she had zero head tilts or episodes of spasms. We will be following up with another neurologist, but our pediatrician's office said this could very well be a reaction to the Hyland Nighttime Teething Tablets and to discontinue use of them right now. I called Hyland's and they said they will be conducting testing on her lot. I would be happy to send you all of her videos if you need to see her reactions and how fast her condition worsened.

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

8/12/15-CT Scan came back perfect (b) (6) -MRI came back perfect and EEG came back perfect with one possible Rapid Eye Movement

---

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. Was not premature. Has never been ill.

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

RX Meds: none.

OTC Meds: We just used Hyland's Nighttime Teething Tablets.

11419862-01-00-01

CaseID: 11419862

...mer Report
...Y reporting of
...uct problems and
product use errors

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 # 611925

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 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)
08/23/2015	08/24/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) 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 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: Hylands teething tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 pills	As needed	Taken by mouth
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 08/23/2015 - 08/23/2015
#2

4. Diagnosis or Reason for Use (Indication)
#1 Teething discomfort
#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
AUG 25 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
Name: (b) (6)
Address:

US

DSS
AUG 25 2

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

11419862-01-00-02

After taking Hylands teething tablets my 8 month old was extremely agitated and had involuntary twitching of her legs and abdomin. She seemed extremely uncomfortable for hours after having consumed them for the first time. I googled side effects and found the FDA warning for belladonna I was previously unaware of and wanted to report the issues we experienced

---

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)*

Race: White

Medical Conditions:

Allergies:

Important Information:

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

11468448-01-00-01

CDER

CaseID: 11468448

...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 #
613618

...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	10 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)
08/21/2015	09/03/2015

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: Hyland's Teething Tablets
Strength: 2-3 tablets
Manufacturer: Hyland Inc

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2-3 tablets/4x a day	Once daily	Taken by mouth
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 08/21/2015 – 08/28/2015
#2

4. Diagnosis or Reason for Use (Indication)
#1 Issues with 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 A29815	#1	54973-3127-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name CTU

3. Manufacturer Name, City and State SEP – 4 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)

See additional page(s) for complete text.

G. REPORTER (See confidentiality section on back)

1. Name and Address
Name: (b) (6)
Address:
City: State: ZIP

US DSS
SEP – 4 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

My baby is now 10 months old and I used the Hyland's Teething Tablets on him for approximately 7-8 days in which during that time, he began to suffer from what began as increasing eye blinks/winking to eye fluttering which turned into full blown eye twitching/spasms which was happening at least every 10-15 minutes throughout the day. Sometimes it occurred more often and often there would be several occurrences at once. I sought out help from his pediatrician who advised to stop the use of the teething tablets. It took about 2 days without any teething tablets and the extent of the twitching began to decrease as well as the frequency. It has been approximately 6 days now without the teething tablets and we were only seeing 2-3 brief twitches throughout the day. As of mid day today as I write this, there have been no twitches. When this first occurred, there were NO other changes in routine, no new foods introduced, no other types of medications, nothing else that we can correlate with the start time of the twitching and nothing else has changed in his or our lifestyle to explain the decrease in the twitching other than the stopping of the use of the tablets. There was also an instance at approximately 3-4 months of age when I used the teething tablets and he experienced body twitching which I did not correlate with the teething tablets until now because that also stopped when he was not taking the tablets. At this time we are unsure if there is any other damage.

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

None yet at this 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: none

Allergies: none

Important Information: none

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

RX Meds: none

OTC Meds: currently-none, previously used Tylenol-prn

11473233-01-00-01

user-facilities,
ors and manufacturers
TORY reporting

Mfr Report # 54973
UF/Importer Report #
OTC
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: / or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	CHILD	☐ 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)*
08/00/2015	08/20/2015

5. Describe Event or Problem
CHILD HAS SEIZURES AFTER USING THE PRODUCT.

Received
SEP 04 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.)*

DSS
SEP - 8 2015

(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	#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)*

(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)

SEP - 4 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.

CaseID: 11473233

11473233-01-00-02

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 ☐ 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)*: 08/17/2015

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 # 1629

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

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SEP - 8 2015

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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.

11473233-01-00-03

COMPLAINT #: 2639

DATE OF COMPLAINT: 08/17/2015

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: N/A

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: (b) (6)

NATURE OF COMPLAINT:

CUSTOMER SENT THE FOLLOWING E-MAIL AND DID NOT RESPOND TO HYLAND'S E-MAIL: MY SONS HAVE BEEN USING THESE TABLETS FOR AWHILE MY OLDEST SONNOW HAS SEIZURES WITHOUT WARNING,HE HAS BEEN TO SEVERAL DOCTORS AND ASKED US TO NAME EVERYTHING HE USES. WHEN I WENT BACK 2 WEEKS LATER. THEY TOLD US AN INGREDIANT YOU USE CAN CAUSE SEIZURES EVENTUALLY LEADING TO THE BRAIN BLEEDING. WHY ARE YOU STILL SELLING THIS PRODUCT? YOU SHOULD INFORM THE PUBLIC OF ITS RISK, I KNOW I AM

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: 08/17/2015

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 #: 1629

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/17/2015

BY: EDYTA FRACKIEWICZ

SEP - 4 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalf

DATE: 08-25-15

BY: Eric Bam
QA / QC DIRECTOR

DATE: 08-25-15

DSS

SEP - 8 2015

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

11473233-01-00-04

INDARD
PATHIC
USA SINCE 1903

Adverse Event
SAE-0038-2015

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-five (135) Adverse Events (AE) which also included forty-nine (49) 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 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

8/24/2015
Date

DSS

SEP - 8 2015

SEP - 4 2015

CC-0675-2015
AE-0389-2015

11473233-01-00-05

11473233

EVENT DATA FORM

AE #: 1629 **COMPLAINT #:** 2639

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

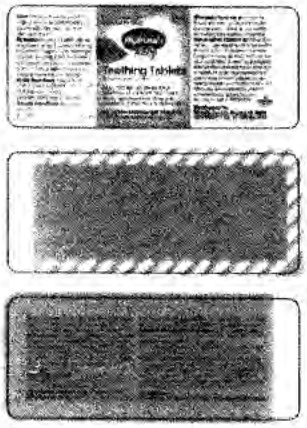
COUNTRY: ZIP CODE:

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

SEP - 8 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Wolf DATE: 08-25-15

SEP - 4 2015

BY: Eric Bain DATE: 08-25-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

11500192-01-00-01

CaseID: 11500192

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

OTC

...ser-facilities,
...rs and manufacturers
...ORY reporting

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

MEDWATCH
FORM FDA 3500A (2/13)

Page 1 of 6

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 ☐ 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)*
08/06 - 08/20/15	08/24/15

5. Describe Event or Problem

CHILD HAVING SYMPTOMS OF HEAD JERKING/DROPPING, TORSO TILTING AND UPPER BODY SPASMS SEVERAL TIMES A DAY. (b) (6) CHILD TAKEN TO THE ER AND ADMITTED TO THE NEUROLOGY DEPARTMENT. CT SCAN, MRI, AND EEG WERE NORMAL. NEUROLOGY UNABLE TO PROVIDE A DEFINITIVE DIAGNOSIS BUT GAVE MOTHER A DIAGNOSIS OF BENIGN PAROXYSMAL TORTICOLLIS AND SPASMUS NUTANS. CHILD CAME HOME FROM THE HOSPITAL AND STOPPED USING THE NIGHTTIME TEETHING TABLETS ON (b) (6) AND HAS HAD FEWER EPISODES AND NO EPISODES ON 8/21/15. F/U 08/25/15-SYMPTOMS RESOLVED AFTER PRODUCT WAS DISCONTINUED. NEUROLOGIST DIAGNOSED AS SEIZURES (NON-EPILEPTIC).

RECEIVED
SEP 10 2015
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

CT Scan, MRI and EEG 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.)*

FAMILY HISTORY OF EPILEPSY, SEIZURES, AND TOURETTES.

(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 NIGHTTIME TEETHING TABLETS

#2 N/A

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 2 TABS QHS X 1 WEEK	#1
#2 N/A	#2

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

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 B31914	#1	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 N/A	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3197-1

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 SEP 10 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)

DSS
SEP 11 2015

Phone # (b) (6)	Email Address

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

11500192-01-00-02

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)*: 08/21/15
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 # 1630

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

SEP 10 2015
DSS
SEP 11 2015

11500192-01-00-03

COMPLAINT #: 2640

DATE OF COMPLAINT: 08/21/2015

PRODUCT: BABY NIGHTTIME TEETHING TABLETS ITEM CODE: BTNT—T135

SIZE: 135 TABS LOT NO.: B31914

REPORTER: (b) (6)

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT:

CUSTOMER POSTED THE FOLLOWING ON(b) (6) WE STARTED USING THE NIGHTTIME TEETHING TABLETS ABOUT 3 WEEKS AGO. MY DAUGHTER HAD "HEAD DROPS" A FEW DAYS AFTER WE STARTED THESE PILLS AND WE TOOK HER TO CHILDREN'S HOSPITAL IN (b) (6) HER EPISODES WERE GETTING MORE FREQUENT AND WORSE. THE PEDIATRICIANS AND NEUROLOGISTS DIDNT KNOW WHAT WAS WRONG AND I HAD FORGOTTEN THAT I HAD BEEN GIVING HER THESE PILLS. I ALSO LEFT YHE BOTTLE AT HOME AND SHE GOT SO MUCH BETTER QUICKLY. AFTER WE RETURNED HOME, I DIDN'T GUVE HER THE PILLS AND SHE HASN'T HAD ANY EPISODES IN THE PAST TWO DAYS. I'M WAITING ON A CALL BACK FROM OUR PEDIATRICIAN ABOUT THIS BEING RELATED TO HER UNEXPLAINED CONDITION, BUT THE TIMING OF HER EPISODES AND THE USE OF THIS MEDICATION LINES UP. WE JUST REALIZED THIS YESTERDAY AFTER ANOTHER MOM ASKED IF WE HAD BEEN USING THESE TABLETS AFTER SEE IN OUR VIDEO. I AM VERY CONCERNED AND UPSET ABOUT THIS. SPOKE WITH THE MOTHER THAT SAME DAY. CHILD STARTED HAVING SYMPTOMS OF HEAD JERKING/DROPPING, TORSO TILTING AND UPPER BODY SPASMS SEVERAL TIMES A DAY. (b) (6) CHILD WAS TAKEN TO THE EMERGENCY ROOM AND ADMITTED TO THE NEUROLOGY DEPARTMENT. CT SCAN, MRI, AND EEG WERE NORMAL. MOTHER TOOK A VIDEO OF HER CHILD DOING THIS. GIVING THE TABLETS 2 TABS QHS X 1 WEEK. STOPPED THE TEETHING TABLETS(b) (6) WHEN CHILD WAS ADMITTED TO THE HOSPITAL. NEUROLOGY SAID THAT THEY DON'T KNOW WHAT THE EXACT DIAGNOSIS IS FOR SURE BECAUSE THEY HAVE NEVER SEEN THIS BEFORE BUT GAVE MOTHER A DIAGNOSIS OF BENIGN PAROXYSMAL TORTICOLLIS AND SPASMUS NUTANS. ONCE THEY CAME HOME FROM THE HOSPITAL AND STOPPED THE TEETHING TABLETS, CHILD HAS HAD FEWER EPISODES. MOTHER HAS READ THAT BELLADONNA CAN CAUSE SPASMS. MOTHER WOULD LIKE TO KNOW HOW TO TEST IF THE TABLETS CAUSED THE SYMPTOMS. MOTHER WANTS A REFUND OF SRP FOR ONE BOTTLE OF BTNT AND ONE BOTTLE OF BTET BECAUSE SHE IS AFRAID TO USE THEM IN HER BABY. SHE IS NOT HAPPY WITH THE PRODUCTS. WANTED TO KNOW IF HYLAND'S WOULD PAY FOR MEDICAL COSTS IF PRODUCT IS DETERMINED TO HAVE CAUSED THE SYMPTOMS IN HER CHILD. I INFORMED THE CUSTOMER THAT I COULD ONLY OFFER A REFUND FOR THE PRODUCT AND WOULD NOT BE ABLE TO AUTHORIZE PAYMENT FOR MEDICAL COSTS. CUSTOMER SAID THAT SHE WILL CALL BACK IN A FEW WEEKS TO ASK ABOUT THE RESULTS OF THE INVESTIGATION OF THE LOT # THAT SHE PROVIDED. MOTHER HAD EPILEPSY AS A CHILD THAT SHE OUTGREW. AUNT HAS GRAND MAL SEIZURES. OTHER FAMILY MEMBERS HAD TOURETTES. GRANDMOTHER HAS A GENETIC BRAIN DISEASE BUT BABY SHOWS NO SIGN OF IT. (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:

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

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

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1630

SEP 10 2015

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: BY:

SECTION V:

REVIEWED BY MANAGEMENT BY: R Wulff DATE: 08-31-15

DSS SEP 11 2015

BY: Dave Brenin QA / QC DIRECTOR DATE: 08-28-15

cc: QA / QC Production

F/U POSTED TO (b) (6)

Hey ladies! Here is my update on my baby girl who I took to the hospital a couple of weeks ago for head drops and spasms. We saw a neurologist today and he said she looks perfect. We have gone 5 days with no symptoms now. The neurologist believes that the nighttime teething tablets we had just started giving her, caused the seizures. He called them seizures but said they weren't epileptic, that they were likely triggered by the magnesium and/or belladonna in the tablets. We had started giving her the nighttime version about 3 days before her seizures became very obvious and I forgot to bring the bottle to the hospital to give her so she had less seizures up there. I gave her a couple of tablets when we got home that next night and the next day she had more seizures. Then I discontinued use and she had less each day than the day prior and now it's been 5 days seizure free. We didn't even think of those tablets causing any issues because she had the regular ones (not nighttime) several times with no reaction. We really believed that they were completely safe to give her because they were natural. We are relieved it was something that is easy to fix and we appreciate everyone's prayers. I will be contacting the company's legal department to complain and push them to put a warning on them that it could trigger a neurological reaction.
Edited to add: She has had an MRI, EEG, CT scan. All came back perfect. I took her to children's hospital where she was looked after by a team of neurologists and I took her to a separate neurologist who diagnosed her. We have looked into every possible condition or cause and the only thing that is possible or likely is that these tablets caused it. The dr especially believes that due to her timing of getting worse lining up with being on the medication for a couple of days and her getting better and becoming symptom free after stopping use.

F/U FROM PHONE CALL WITH (b) (6) 08/26/15

(b) (6) called me today insisting to speak with the legal department. She stated that she gave you a report last week about her child having seizures from the nighttime teething tablets. She said that she had gone to the ER and that the ER could not figure out what was wrong. She said the ER took a video and that she posted it on lots of moms groups and that it has 40,000 views in 12 hours. She said she took her child to a neurologist who told her he believes it is from the tablets specifically the mag phos and belladonna. She said that the neurologist says they are non-epileptic seizures since the child had 4 while on EEG and that they did not show up on the EEG. She says she owes a lot of money in hospital bills and that she is not going away. She also said the kids are napping and now is a good time to call. I told her I would have someone in management get back to her by end of business today. She said also said there should be a warning label on the tablets. I asked her phone number and state she was calling from. She said (b) (6) and phone (b) (6)

Individual Case Safety Report

11500192-01-00-04

SEP 10 2015

DSS SEP 11 2015

11500192-01-00-05

...e Event

SAE-0039-2015

Product in Inventory:

No (0) units of Hyland's Baby Nighttime Teething Tablets (BTNT), lot # B31914, 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 Nighttime Teething Tablets (BTNT), lot # B31914, 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 Nighttime Teething Tablets (BTNT), lot # B31914,. The Nighttime Baby Teething bulk lot # 125307 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 and not other complaints for this lot have been reported.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Nighttime Teething Tablets (BTNT), lot # B31914.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

8/25/2015
Date

SEP 10 2015

DSS SEP 11 20

11500192-01-00-06

DATA FORM

AE #: 1630 **COMPLAINT #:** 2640

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: 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: R Wulf DATE: SEP 10 2015 08/31/15

BY: Eric Baum DATE: 08-28-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

11513415-01-00-01

umer Report CDER

CaseID: 11513415

Form Approved: OMB No. 0910-0291. Expires: 12/31/2011
See OMB statement on reverse

Y reporting of
luct problems and
product use errors

12

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence #
614808

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	15 Months (b) (6)	☐ Female ☑ Male	29.6 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)*
09/10/2015	09/14/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) 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 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: Hyland Baby teething tablets
Strength:
Manufacturer: Hyland's Inc.

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2-3	As needed	Taken by mouth
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 09/04/2015 - 09/10/2015
#2

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

6. Lot #	7. Expiration Date
#1 B00215	#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

SEP 15 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
SEP 15 20

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

11513415-01-00-02

On (b)(6) My 15 month son had a seizure a hour after taking this product. I gave him two tablets. He was taken to the hospital immediately.

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)*

Race: --

Medical Conditions: none

Allergies: none

Important Information:

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

Form Approved: OMB No. 0910-0291 Expires: 6/30/2015
See OMB Statement on Reverse.

11516350-01-00-01

...ıser-facilities,
...ors and manufacturers
...ORY reporting

Mfr Report # 54973

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)	CHILD	☐ 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)*
00/00/0000	09/03/15

5. Describe Event or Problem

REPORTER POSTED ON (b) (6) CHILD HAD SEIZURES WHEN THEY TOOK THE TABLETS.

(Continue on page 3)

Received
SEP 15 2015
CDR

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 NIGHTTIME TEETHING TABLETS

#2 N/A

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

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF NITE TEETHING PAIN

#2 N/A

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 N/A	#1
#2 N/A	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3197-1

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

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

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)* SEP 16 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

Phone #	Email Address

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

SEP 15 2015

CaseID: 11516350

11516350-01-00-02

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)*: 08/31/15

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 # 1637

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 16 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."

SEP 15 2015

CaseID: 11516350

11516350-01-00-03

COMPLAINT #: 2647

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 08/31/2015

PRODUCT: HYLAND'S BABY NIGHTTIME TEETHING TABLETS

ITEM CODE: BTNT----T135

SIZE: 135 TABS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (b) (6) AND DID NOT RESPOND TO HYLAND'S REQUEST TO CONTACT HYLAND'S: MY SO'S EX'S CHILD HAD SEIZURES WHEN THEY TOOK THE TEETHING TABS.

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**: 08/31/2015

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 #: 1637

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/31/2015

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWulf

DATE: 09-09-15

BY: Eric Baum
QA / QC DIRECTOR

DATE: 09-08-15

DSS SEP 16 201

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

SEP 15 2015

11516350-01-00-04

NDARD PATHIC
USA SINCE 1903

Serious Adverse Event
SAE-0046-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 nine (9) Adverse Events (AE) which also included eight (8) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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

9/3/2015
Date

DSS
SEP 16 2015

SEP 15 2015

CaseID: 11516350

11516350-01-00-05

E EVENT DATA FORM

AE #: 1637 **COMPLAINT #:** 2647

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

NAME: UNKNOWN

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: DATE: 09-09-15

DSS SEP 16 2015

BY: DATE: 09-08-15

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

SEP 15 2015

11516352-01-00-01

CaseID: 11516352

Form Approved: OMB No. 0910-0291 Expiration Date: 03/30/2015
See OMB statement on reverse.

user-facilities,
ors and manufacturers
TORY reporting

Mfr Report # 54973	OTC
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	CHILD	☐ 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)*
00/00/0000	09/02/15

5. Describe Event or Problem

(b) (6) REPORTER POSTED ON MOTHER GAVE THE TABLETS TO THE CHILD AND SHORTLY AFTERWARDS HE STARTED VOMITING AND HIS TEMPERATURE WENT UP TO 104 DEG FAHRENHEIT. DOCTORS SAW WAX BUILD UP IN HIS EAR, SO THEY LABELED IT AS AN EAR INFECTION, BUT THEY SAW NO ACTUAL INFECTION.

RECEIVED SEP 15 2015 CDR

(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 NIGHTTIME TEETHING TABLETS

#2 N/A

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

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

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

9. NDC# or Unique ID: 54973-3197-1

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 DSS SEP 16 2015

Phone #	Email Address

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

SEP 15 2015

11516352-01-00-02

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)*
08/27/15

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)
HIGH FEVER, VOMITING, EAR INFECTION

9. Manufacturer Report Number
54973 AE # 1636

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 16 2015
SEP 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

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: 11516352

11516352-01-00-03

COMPLAINT #: 2646

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 08/27/2015

PRODUCT: HYLAND'S BABY NIGHTTIME TEETHING TABLETS

ITEM CODE: BTNT----T135

SIZE: 135 TABS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT:

CUSTOMER POSTED THE FOLLOWING (b) (6) POST IN RESPONSE TO A BABY NIGHTTIME TEETHING TABLETS POST AND DID NOT CONTACT HYLAND'S DIRECTLY TO PROVIDE MORE INFORMATION: HAS ANYONE HAD ANY ISSUES WITH HIGH FEVER AFTER THESE TABLETS? I GAVE MY SON TABLETS AND SHORTLY AFTERWARDS HE STARTED VOMITING AND HIS TEMP WENT UP TO 104. THE DOCTOR DOESN'T KNOW WHAT'S WRONG. THEY SAW WAX BUILD UP IN HIS EAR, SO THEY LABELED IT AS AN EAR INFECTION, BUT THEY SAW NO ACTUAL INFECTION.

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**: 08/27/2015

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 #: 1636

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/27/2015

BY: EDYTA FRACKIEWICZ

DSS

SEP 16 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: Rebekah

DATE: 09-09-15

BY: Eric Bain

QA / QC DIRECTOR

DATE: 09-08-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

SEP 15 2015

11516352-01-00-04

NDARD PATHIC USA SINCE 1903

Serious Adverse Event
SAE-0045-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 eight (8) Adverse Events (AE) which also included seven (7) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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

9/3/2015
Date

DSS
SEP 16 2015

SEP 15 2015

11516352-01-00-05

SE EVENT DATA FORM

AE #: 1636 **COMPLAINT #:** 2646

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:

REVIEWED BY MANAGEMENT BY: R Walt DATE: 09-09-15

BY: Eric Bain DATE: 09-08-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

DSS SEP 16 201

SEP 15 2015

CaseID: 11516354

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

11516354-01-00-01

y user-facilities,
utors and manufacturers
ATORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

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: 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)
- [ ] 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): 00/00/0000

4. Date of This Report (mm/dd/yyyy): 09/02/15

5. Describe Event or Problem

REPORTER POSTED ON (b) (6) PRODUCT CAUSED THE CHILD TO HAVE SEIZURES AND TO BE HOSPITALIZED AND HAVE A NUMBER OF TESTS PERFORMED.

(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 NIGHTTIME TEETHING TABLETS
#2 N/A

2. Dose, Frequency & Route Used
#1 UNKNOWN
#2 N/A

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

4. Diagnosis for Use (Indication)
#1 TEMP RELIEF NITE TEETHING PAIN
#2 N/A

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

6. Lot #
#1 N/A
#2 N/A

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
54973-3197-1

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)

Phone #

Email Address

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

3. Occupation: NA

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

CaseID: 11516354

11516354-01-00-02

FDA USE ONLY

of 5

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)*: 08/29/15

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 # 1635

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 16 2015

SEP 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

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: 11516354

11516354-01-00-03

COMPLAINT #: 2645

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 08/29/2015

PRODUCT: HYLAND'S BABY NIGHTTIME TEETHING TABLETS

ITEM CODE: BTNT----T135

SIZE: 135 TABS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING (b) (6) POST IN RESPONSE TO A POST ABOUT BABY NIGHTTIME TEETHING TABLETS: THESE HAVE ALSO CAUSED MY DAUGHTER TO HAVE SEIZURES AT 7 MONTHS OLD, WAS HOSPITALIZED AND HAD NUMBERS OF TEST DONE TO HER, YES IT MAY NOT HAVE HAPPENED TO EVERY CHILD BUT IT HAS HAPPENED TO MORE CHILDREN THEN YOU THINK. DO YOUR RESEARCH. BCUS WHO WANTS TO RIDE IN A AMBULANCE TO THE NEAREST HOSPITAL THAT'S AN HOUR AWAY WITH YOUR CHILD SCREAMING AND YOU CANT DO ANYTHING ABOUT IT? OR NUMBERS IT TEST, TO BE TOLD SOMETHING SO NATURAL GAVE MY CHILD 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 INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 08/29/2015

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 #: 1635

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/29/2015 BY: EDYTA FRACKIEWICZ

DSS

SEP 16 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: RWdH DATE: 09-09-15

BY: Eric Bain QA / QC DIRECTOR DATE: 09-08-15

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

Form # VD1

SEP 15 2015

11516354-01-00-04

NDARD PATHIC USA SINCE 1903

...dverse Event
SAE-0044-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 seven (7) Adverse Events (AE) which also included six (6) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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

9/3/2015
Date

DSS
SEP 16 2015

CC-0714-2015
AE-0409-2015

SEP 15 2015

CaseID: 11516354

11516354-01-00-05

EVENT DATA FORM

AE #: 1635 **COMPLAINT #:** 2645

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
SEP 16 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWulf DATE: 09-09-15

BY: Eric Bain DATE: 09-08-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

SEP 15 2015

Form Approved: OMB No. 0910-0291 Expires: 6/30/2015
See OMB statement on reverse.

11516357-01-00-01

user-facilities,
ors and manufacturers
ORY reporting

Mfr Report # 54973

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)	INFANT	☐ 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)*
00/00/2015	08/31/15

5. Describe Event or Problem

CHILD HAD SEIZURES AROUND THE TIME HE WAS USING THE PRODUCT. THE SEIZURES RESOLVED WHEN THE PRODUCT WAS DISCONTINUED.

(Continue on page 3)

Received
SEP 15 2015
CDR

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 NIGHTTIME TEETHING TABLETS

#2 N/A

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

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

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

9. NDC# or Unique ID: 54973-3197-1

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

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
USA
SEP 16 2015

Phone #	Email Address

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

SEP 15 2015

CaseID: 11516357

11516357-01-00-02

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 Address: HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061 Email Address: STANDARD@HYLANDS.COM	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
08/29/15	

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	8. Adverse Event Term(s)
54973 AE # 1634	SEIZURES

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?	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. 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 SEP 15 2015

SEP 16 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."

CaseID: 11516357

11516357-01-00-03

COMPLAINT #: 2644

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 08/29/2015

PRODUCT: HYLAND'S BABY NIGHTTIME TEETHING TABLETS

ITEM CODE: BTNT----T135

SIZE: 135 TABS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT:

CUSTOMER POSTED THE FOLLOWING MESSAGE ON (b) (6) AND DID NOT CONTACT HYLAND'S TO PROVIDE MORE INFORMATION: I'M ACTUALLY VERY GLAD I CAME ACROSS THIS. A FEW MONTHS BACK I BROUGHT MY SON IN FOR WHAT I THOUGHT WAS SEIZURES. AROUND THAT SAME TIME HE WAS USING THIS SAME PRODUCT AND ONCE WE STOPPED GIVING TO HIM, EVERYTHING STOPPED AND THERE WAS NO NEED FOR TESTS. HE'S BEEN PERFECTLY FINE EVER SINCE WE STOPPED USING HYLANDS TABLETS. BUT I NEVER THOUGHT THAT THEY COULD BE THE CAUSE.

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**: 08/29/2015

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 #: 1634

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/29/2015

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWelt

DATE: 09-02-15

DSS SEP 16 2015

BY: Gina Bram
QA / QC DIRECTOR

DATE: 09-02-15

SEP 15 2015

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

11516357-01-00-04

VDARD ATHIC SA SINCE 1903

Serious Adverse Event
SAE-0043-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 six (6) Adverse Events (AE) which also included five (5) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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

9/2/2015
Date

DSS
SEP 16 2015

SEP 15 2015

11516357-01-00-05

EVENT DATA FORM

AE #: 1634 **COMPLAINT #:** 2644

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: 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 16 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 09-02-15

BY: DATE: 09-02-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

SEP 15 2015

CaseID: 11516369

11516369-01-00-01

Form Approved: OMB No. 0910-0291 Expiration Date: 03/30/2015
See OMB statement on reverse.

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

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

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: INFANT 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)*
00/00/2015	08/31/15

5. Describe Event or Problem

CUSTOMER GAVE HER CHILD THE TABLETS ON TWO OCCASIONS AND HE HAD TWO HEAD DROPS IN THE DAY AFTER RECEIVING THEM.

(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.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

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

#1 HYLAND'S BABY NIGHTTIME TEETHING TABLETS

#2 N/A

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

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

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

9. NDC# or Unique ID: 54973-3197-1

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)

DSS USA
SEP 16 2015

Phone #	Email Address SEP 15 2015

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

Received
SEP 15 2015
CDR

CaseID: 11516369

11516369-01-00-02

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 ☐ 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)*: 08/27/15

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): HEAD DROPS

9. Manufacturer Report Number: 54973 AE # 1633

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 16 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."

SEP 15 2015

11516369-01-00-03

COMPLAINT #: 2643

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 08/27/2015

PRODUCT: HYLAND'S BABY NIGHTTIME TEETHING TABLETS

ITEM CODE: BTNT----T135

SIZE: 135 TABS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT:

CUSTOMER POSTED THE FOLLOWING TWO MESSAGES ON (b) (6) AND DID NOT CONTACT HYLAND'S TO PROVIDE MORE INFORMATION: POST #1: I HAD GIVEN MY SON THE NIGHT TIME TABLETS ON 2 DIFFERENT OCCASIONS AND HE HAD 2 HEAD DROPS IN THE DAYS AFTER I HAD GIVEN THEM TO HIM. I THOUGHT SOMETHING WAS UP BUT HE DIDN'T DO IT AGAIN..AND I DIDN'T USE THE TABLETS AFTER THAT. I REALLY HOPE YOUR LITTLE ONE WILL BE ALRIGHT, THIS SCARES ME SO MUCH. POST #2: I WILL BE FOLLOWING Y'ALL'S STORY.. I CAN'T HELP FINANCIALLY BUT I AM ON YOUR SIDE !!!! MY SON ONLY TOOK THE TABLETS TWICE BUT HAD THE SAME HEAD DROPS YOUR DAUGHTER HAS.. I DIDN'T KNOW WHAT TO THINK AT THE TIME BUT SEEING THIS IT SCARES THE HELL OUT OF ME TO THINK I HAVE HIM SOMETHING THAT DID THAT TO HIM.

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**: 08/27/2015

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 #: 1633

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/27/2015

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 09-02-15

DSS SEP 16 2015

BY:

QA / QC DIRECTOR

DATE: 09-02-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

SEP 15 2015

11516369-01-00-04

NDARD
PATHIC
SA SINCE 1903

Serious Adverse Event
SAE-0042-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 five (5) Adverse Events (AE) which also included four (4) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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

9/2/2015
Date

DSS
SEP 16 2015

SEP 15 2015

CaseID: 11516369

11516369-01-00-05

EVENT DATA FORM

AE #: 1633 **COMPLAINT #:** 2643

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
SEP 16 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DWilt DATE: 09-02-15

BY: Eric Bain DATE: 09-02-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

SEP 15 2015

Form Approved: OMB No. 0910-0291 Expiration Date: 06/30/2015
See OMB statement on reverse.

11516392-01-00-01

user-facilities,
tors and manufacturers
TORY reporting

Mfr Report # 54973

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)	INFANT	☐ 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)*
00/00/2012	08/31/2015

5. Describe Event or Problem

MOTHER USED LESS THAN THE RECOMMENDED DOSE AND BABY STARTED SEIZING AND SPASMING. RESOLVED.

(Continue on page 3)

Received
SEP 15 2015
CDR

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.)*

(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	#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)*

(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)

DSS
SEP 16 2015
USA

Phone #	Email Address

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

SEP 15 2015

CaseID: 11516392

11516392-01-00-02

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)*: 08/27/2015

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): SEIZING, SPASMING

9. Manufacturer Report Number: 54973 AE # 1632

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 16 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."

SEP 15 2015

11516392-01-00-03

COMPLAINT #: 2642

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 08/27/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: N/A

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (b) (6) AND DID NOT CONTACT HYLAND'S BY PHONE:
MY SON IS NOW 3 WHEN HE WAS A BABY AND ONLY A FEW MONTHS OLD AND TEETHING I TRIED HYLANDS TEETHING TABLETS. I DIDN'T EVEN USE THE FULL SUGGESTED DOSE AND MY BABY STARTED SEIZING OR SPASMING. I STOPPED IMMEDIATELY. THEN THE SIDE EFFECTS STOPPED. FROM THEN ON I ONLY USED FROZEN PACIFIERS TO SOOTH HIS TEETHING. I AM CONVINCED THOSE TABLETS WERE THE CAUSE AS HE IS A PERFECT LITTLE BOY. AND HAS NEVER DONE THAT BEFORE OR AFTER I STOPPED THOSE.

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**: 08/27/2015

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 #: 1632

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/27/2015 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWdM

DATE: 09-02-15

DSS SEP 16 2015

BY: Eric Bain
QA / QC DIRECTOR

DATE: 09-02-15

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VD1

SEP 15 2015

11516392-01-00-04

NDARD PATHIC USA SINCE 1903

Adverse Event

SAE-0041-2015

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-six (136) Adverse Events (AE) which also included fifty (50) 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 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

9/2/2015
Date

DSS
SEP 16 2015

SEP 15 2015

CaseID: 11516392

11516392-01-00-05

SE EVENT DATA FORM

AE #: 1632 **COMPLAINT #:** 2642

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
SEP 16 20

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 09-03-15
SEP 15 2015

BY: QA / QC DIRECTOR DATE: 09-02-15

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

Form Approved: OMB No. 0910-0291 Expiration Date: 6/30/2015
See OMB statement on reverse.

11516404-01-00-01

y user-facilities,
utors and manufacturers
ATORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

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: 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)*: 04/01/2015

4. Date of This Report *(mm/dd/yyyy)*: 08/28/15

5. Describe Event or Problem

CHILD STOPPED BREATHING, HAD NO PULSE, AND HAD TO BE RESUSCITATED. NO SEQUELAE.

(Continue on page 3)

Received
SEP 15 2015
CDR

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 NIGHTTIME TEETHING TABLETS

#2 N/A

2. Dose, Frequency & Route Used

#1 UNKNOWN

#2 N/A

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

#1

#2

4. Diagnosis for Use *(Indication)*

#1 TEMP RELIEF NITE TEETHING PAIN

#2 N/A

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1 N/A

#2 N/A

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: 54973-3197-1

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 USA
SEP 15 2015
SEP 16 2015

Phone # | Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

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

11516404-01-00-02

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)*: 08/25/15

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): LACK OF VITAL SIGNS

9. Manufacturer Report Number: 54973 AE # 1631

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 16 2015
SEP 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."

CaseID: 11516404

11516404-01-00-03

COMPLAINT #: 2641

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 08/25/2015

PRODUCT: HYLAND'S BABY NIGHTTIME TEETHING TABLETS

ITEM CODE: BTNT---T135

SIZE: 135 TABS

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT:

CUSTOMER POSTED THE FOLLOWING ON (b) (6) AND DID NOT CONTACT HYLAND'S BY PHONE TO PROVIDE MORE INFORMATION: MY NIECE USED NIGHT TIME TEETHING TABLETS AND STOPPED BREATHING HAD NO PULSE. THEY HAD TO RESUSCITATE HER SHE IF FINE NOW, BUT THEY NOW STAY AWAY FROM ALL MEDICATIONS WITH HER. SHE IS A YEAR NEXT MONTH, THIS HAPPENED WHEN SHE WAS 7 MONTHS.

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**: 08/25/2015

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 #: 1631

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 08/25/2015 BY: EDYTA FRACKIEWICZ

DSS

SEP 16 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 09-03-15

BY: Eric Bam QA / QC DIRECTOR DATE: 09-02-15

SEP 15 2015

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

Form # VD1

11516404-01-00-04

VDARD ATHIC SA SINCE 1903

Serious Adverse Event
SAE-0040-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 four (4) Adverse Events (AE) which also included three (3) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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

9/2/2015
Date

DSS
SEP 16 2015

SEP 15 20

11516404-01-00-05

SE EVENT DATA FORM

AE #: 1631 COMPLAINT #: 2641

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: 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 16 201

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Wall DATE: 09-02-15

SEP 15 20

BY: Eric Baun DATE: 09-02-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Form Approved: OMB No. 0910-0291 Expiration Date: 06/30/2015
See OMB statement on reverse.

11516539-01-00-01

...ser-facilities,
...rs 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: (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): 00/00/2009

4. Date of This Report (mm/dd/yyyy): 09/04/15

5. Describe Event or Problem

MOTHER REPORTED ON THE NEWS STATION (b) (6) IN (b) (6) THAT CHILD TOOK ONE DOSE OF THE HYLAND'S TEETHING TABLETS AND WAS OFF, NOT REALLY ACTING HIMSELF, SORT OF OUT OF IT AND THEN HE STARTED VOMITING. HE STARTED TURNING COLORS, STOPPED BREATHING AND HIS EYES WERE ROLLING IN THE BACK OF HIS HEAD. HIS PUPILS WERE LIKE MARBLES WITH BIG BLACK EYES. CHILD WAS TAKEN BY AMBULANCE TO A HOSPITAL, EXAMINED, AND SYMPTOMS RESOLVED.

RECEIVED
SEP 15 2015
CDR

(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 TEETHING TABLETS
- #2 N/A

2. Dose, Frequency & Route Used
- #1 1 DOSE IN 2009
- #2 N/A

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 N/A

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

6. Lot #
- #1 N/A
- #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)

DSS

(Continue on page 3)

SEP 15 2015

E. INITIAL REPORTER

1. Name and Address
(b) (6)

DSS
SEP 16 2015

Phone #

Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

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

SEP 15 2015

CaseID: 11516539

11516539-01-00-02

1 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)*
09/03/15

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)
STOPPED BREATHING, SEIZURES

9. Manufacturer Report Number
54973 AE # 1641

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 16 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.

SEP 15 2015

CaseID: 11516539

11516539-01-00-03

COMPLAINT #: 2651

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 09/03/2015

PRODUCT: HYLAND'S TEETHING TABLETS

ITEM CODE: TEET

SIZE: N/A

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT:

THIS NEWS STORY APPEARED ON (b) (6) (b) (6) ACCORDING THE NEWS STORY MOTHER STATED THAT AFTER GIVING CHILD A DOSE OF TEETHING TABLETS: "HE JUST WAS KIND OF 'OFF', NOT REALLY ACTING HIMSELF, SORT OF OUT OF IT. AND THEN HE STARTED VOMITING. HE STARTED TURNING COLORS AND I SAID, HE IS NOT REALLY BREATHING AND WE WERE TRYING TO TALK TO HIM AND HIS EYES WERE ROLLING IN THE BACK OF HIS HEAD. HIS PUPILS WERE LIKE MARBLES, JUST BIG BLACK EYES." CHILD WAS RUSHED BY AMBULANCE TO A HOSPITAL. "THEY CHECKED HIM OUT AND HE EVENTUALLY WAS OK. THE ER DOCTOR WAS FAMILIAR WITH THE TEETHING TABLETS AND TOLD ME TO DO SOME RESEARCH ON IT AND WHAT HE SAID WAS BELLADONNA IN LATIN WAS 'BEAUTIFUL LADY' AND PEOPLE TOOK SOME OF THAT PLANT TO BE MORE ATTRACTIVE BECAUSE IT WOULD DILATE THEIR PUPILS."

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**: 09/03/2015

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 #: 1641

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/03/2015

BY: EDYTA FRACKIEWICZ

DSS SEP 16 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt

DATE: 09-11-15

BY: Eric Bain
QA / QC DIRECTOR

DATE: 09-11-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

SEP 15 2015

11516539-01-00-04

NDARD PATHIC USA SINCE 1903

Serious Adverse Event
SAE-0050-2015

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 nine (9) Adverse Events (AE) which also included eight (8) 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

9/10/2015
Date

DS
SEP 15 2015 SEP 16

11516539-01-00-05

EVENT DATA FORM

AE #: 1641 **COMPLAINT #:** 2651

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:

DSS
SEP 16 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 09-11-15

SEP 15 2015

BY: Eric Bain DATE: 09-11-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Form Approved: OMB No. 0910-0291 Expiration Date: 06/30/2015
See OMB statement on reverse.

11516540-01-00-01

y user-facilities,
itors and manufacturers
ATORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

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: 5 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)*: 08/26/2015; 08/28/2015

4. Date of This Report *(mm/dd/yyyy)*: 09/04/15

5. Describe Event or Problem

REPORTER SENT BY E-MAIL A MESSAGE THAT AFTER GIVING HER CHILD ONE DOSE OF BABY TEETHING TABLETS ON 8/26/15 WITHIN 2 HOURS THE CHILD STOPPED BREATHING. ON (b) (6) MOTHER GAVE THE CHILD ANOTHER DOSE OF BABY TEETHING TABLETS AND SHE HAD 3 SEIZING EPISODES WITHIN 15 MINS. CHILD WAS TAKEN TO THE HOSPITAL. CHILD HAD TESTS BUT DOCTORS COULD NOT DETERMINE CAUSE OF THE EPISODES. 09/04/15 FOLLOW UP BY PHONE: TABLETS WERE DISCONTINUED. SYMPTOMS HAVE NOT RETURNED.

(Continue on page 3)

Received
SEP 15 2015
CDR

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.)*

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 N/A

2. Dose, Frequency & Route Used
#1 1 DOSE X 2 DAYS
#2 N/A

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 N/A

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

6. Lot #
#1 A43515
#2 N/A

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

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

DSS
SEP 16 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)

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.

SEP 15 2015

11516540-01-00-02

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
☐ 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)*: 09/02/15

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)
STOPPED BREATHING, SEIZURES

9. Manufacturer Report Number
54973 AE # 1640

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 16 2015

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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 15 2015

CaseID: 11516540

11516540-01-00-03

COMPLAINT #: 2650

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 09/02/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABS

LOT NO.: A43515

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT:

CUSTOMER SENT THE FOLLOWING E-MAIL MESSAGE: I JUST READ YOUR UPDATED RECALL ARTICLE & AS A NEW MOTHER OF A LITTLE GIRL THAT IS NOW MY LIFE, I BEG YOU TO PUT A WARNING LABEL ON YOUR PRODUCT! LAST WEEK I BEGAN GIVING MY ALMOST 5 MONTH OLD YOUR TEETHING TABLETS. ON TUESDAY, I GAVE HER ONE DOSE AND WITHIN 2 HOURS SHE STOPPED BREATHING. ON (b) (6) I GAVE HER ANOTHER DOSE AND SHE HAD 3 SEIZING EPISODES WITHIN 15 MINS! WE HAD TO RUSH HER TO THE HOSPITAL. AFTER SEVERAL TESTS, DOCTOR'S COULD NOT EXPLAIN WHY SHE HAD THE EPISODES. I'M NOT ASKING YOUR COMPANY TO REMOVE THE PRODUCT, AS MANY CHILDREN I KNOW HAVE TAKEN THE TABLETS WITH NO REACTION. I'M JUST BEGGING TO PUT A WARNING LABEL ON THEM IN CASE CHILDREN DO HAVE EPISODES, IT WILL CLICK FOR PARENTS TO DISCONTINUE THE USE OF THEM. IMAGINE IF IT WAS YOUR CHILD....
CUSTOMER RESPONDED ON 9/3/2015 WITH THE FOLLOWING INFORMATION: I'M NOT SURE WHERE TO LOCATE THE LOT #. I'M SEEING 2 NUMBERS IN THE BOTTLE. ONE IS DARK BLACK BOLD A43515. ANOTHER ONE READS NDC 54973-3127-1.
09/04/15 F/U BY PHONE: NKA. NO FAMILY HX OF SEIZURES. NO FEVER, NO ILLNESS. SEIZURES HAVE STOPPED WHEN TABLETS WERE STOPPED. DOCTOR COULD NOT FIND A REASON FOR THE SEIZURES. TAKEN TO THE ER AND RELEASED. NO PREEXISTING CONDITIONS.

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**: 09/02/2015

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 #: 1640

ADVERSE EVENT SERIOUS: (Y) / N

DSS SEP 16 2015

ADVERSE EVENT REPORTED ON: 09/02/2015 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: Rwalt DATE: 09-11-15

BY: Gina Bann QA / QC DIRECTOR DATE: 09-11-15 SEP 15 2015

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

Form # VD1

11516540-01-00-04

NDARD
PATHIC
SA SINCE 1903

Serious Adverse Event
SAE-0049-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A43515, 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 # A43515 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 # A43515. The Baby Teething bulk lot # 125412 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 complaints (CC-0337-2015, CC-0434-2015 & CC-0578-2015) have been received for Hyland's Baby Teething Tablets lot # A43515. 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 # A43515.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

9/16/2015
Date

DSS
SEP 16 2015

SEP 15 2015

11516540-01-00-05

SE EVENT DATA FORM

AE #: 1640 **COMPLAINT #:** 2650

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: 09-11-15

BY: QA / QC DIRECTOR DATE: 09-11-15

DSS
SEP 16 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

SEP 15 2015

FORM SAE01

Form Approved: OMB No. 0910-0291 Expires: 6/30/2015
See OMB statement on reverse.

11516601-01-00-01

...user-facilities,
...tors and manufacturers
...TORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

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: 5 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)*: 07/14/2015 - PRESENT

4. Date of This Report *(mm/dd/yyyy)*: 09/04/15

5. Describe Event or Problem

CHILD STARTED EXPERIENCNG SEIZURE LIKE ACTIVITY FOLLOWING USE OF BABY TEETHING TABLETS AND THE SYMPTOMS OCCUR ONE OR TWO TIMES PER WEEK. STOPPED USING THE BABY TEETHING TABLETS ON 07/14/15 BUT SYMPTOMS ARE CONTINUING. EPISODES LOOK LIKE CHILD IS NODDING HIS HEAD AND ARMS CURL UP TO HIS CHEST AND HE SHAKES THEM. DOCTORS ARE PERFORMING TESTS.

(Continue on page 3)

Received
SEP 15 2015
CDR

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 N/A

2. Dose, Frequency & Route Used
- #1 2 TABS SL BID X 3 WEEKS
- #2 N/A

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 N/A

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

6. Lot #
- #1 A68015
- #2 N/A

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: ☐ 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
SEP 16 2015

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.

SEP 15 2015

11516601-01-00-02

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)*: 09/01/15

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 # 1638

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 16 2015

SEP 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."

CaseID: 11516601

11516601-01-00-03

COMPLAINT #: 2648

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 09/01/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABS

LOT NO.: A68015

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT:

CUSTOMER SENT THE FOLLOWING E-MAIL: AFTER USING YOUR RECOMMENDED PRODUCT MY SON STARTED HAVING SEIZURE LIKE ACTIVITY AND YOUR PRODUCT IS THE ONLY THING THAT WAS ADDED TO MY SONS DIET AND THESE SEIZURES STARTED JULY 14TH AND HE HAS ABOUT ONE TO TWO A WEEK, I HAVE NO LONGER BEEN USING YOUR PRODUCTS AND I CAN ASSURE YOU I HAVE TOLD EVERYONE AND WILL CONTINUE TO TELL EVERYONE TO NEVER USE YOUR PRODUCTS. MY SON HAS BEEN IN AND OUT OF THE HOSPITAL FOR THIS REOCCURRING ISSUE. YOU CAN FEEL FREE TO CONTACT ME AND I WILL BE CONTACTING A LAWYER TO TAKE LEGAL ACTION AGAINST YOUR COMPANY. ON 9/2/15 CUSTOMER SENT THE FOLLOWING MESSAGE AND INCLUDED HER PHONE NUMBER: THE NUMBER ON THE BOTTLE SAYS NDC 54973-3127-1.THERE IS ALSO A NUMBER ON THE SIDE OF THE BOTTLE A68015.
I SPOKE TO THE CUSTOMER'S HUSBAND ON 9/3/2015: SYMPTOMS DESCRIBED AS SEIZURE LIKE ACTIVITY. HAS BEEN TO THE DOCTOR AT (b) (6) (b) (6) AND THEY ARE RUNNING TESTS. STOPPED USING THE BABY TEETHING TABLETS ON JULY 14TH. GIVING 2 TABS BID X 3 WEEKS. EPISODES LOOK LIKE CHILD IS NODDING HIS HEAD AND ARMS CURL UP TO HIS CHEST AND HE SHAKES THEM. I OFFERED A REFUND AND CUSTOMER DECLINED.

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**: 09/01/2015

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

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS SEP 16 2015

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1638

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/01/2015 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 09-11-15

BY:

QA / QC DIRECTOR

DATE: 09-11-15 SEP 15 2015

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

11516601-01-00-04

NDARD PATHIC
USA SINCE 1903

Serious Adverse Event
SAE-0047-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A68015, 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 # A68015 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 # A68015. The Baby Teething bulk lot # 125644 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-0612-2015 & CC-0672-2015) have been received for Hyland's Baby Teething Tablets lot # A68015. 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 # A68015.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

9/16/2015
Date

DSS
SEP 16 2015

11516601-01-00-05

SE EVENT DATA FORM

AE #: 1638 **COMPLAINT #:** 2648

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: 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 16 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 09-11-15

BY: QA / QC DIRECTOR DATE: 09-11-15

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

SEP 15 2015

Individual Case Safety Report

11536908-01-00-01

CaseID: 11536908

: Report

eporting of problems and rors

Form Approved OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence #

615528

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	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)*
09/17/2015	09/19/2015

5. **Describe Event, Problem or Product Use Error**

See additional page(s) 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 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: Hyland's teething tablets
Strength:
Manufacturer: Hyland

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	Four times daily	--
#2		

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

#1 09/16/2015 - 09/18/2015
#2

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

#1 Teething pain
#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**

SEP 21 2015

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

SEP 21 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

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.

11536908-01-00-02

My 10 month year old son used Hyland's teething tablets, he is experiencing lethargy muscle weakness constipation and skin flushing.

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)*

Race: Hispanic/Latino

Medical Conditions:

Allergies:

Important Information:

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

Individual Case Safety Report

11544456-01-00-01

CaseID: 11544456

1/2

Report

porting of
roblems and
ors

OTC

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence #

615991

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	13 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)*
☑ 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)*
09/19/2015	09/22/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) 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 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: Hyland's teething tablets
Strength: Hyland's teething tablets
Manufacturer: Hyland

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	Twice daily	Taken by mouth
#2		

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

#1
#2

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

#1 My son was 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

SEP 23 2015

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 additional page(s) for complete text.

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

1. Name and Address

(b) (6)

OSS

SEP 23 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

11544456-01-00-02

On (b)(6) at 3:30 am my thirteen month old son had a seizure due from a high fever. Around 1am he woke up with teething pain and I had given him two Hyland's teething tablets to help with the pain, two and a half hours later I had to call 911 where an ambulance came to my home and transported him to the hospital.

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)*

Race: White

Medical Conditions:

Allergies:

Important Information:

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

RX Meds:

OTC Meds: Hyland's teething tablets Hyland's Cold medicine ALL STOPPED BEING USED.

Form Approved: OMB No. 0910-0291 Expires: 6/30/2015
See OMB Statement on reverse.

CaseID: 11603023

11603023-01-00-01

user-facilities,
ors and manufacturers
TORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

OTC

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 ____ 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)*
9/11/2015	09/15/15

5. Describe Event or Problem

CHILD RECEIVED A DOSE OF 2 TABLETS AND WITHIN AN HOUR THE CHILD WAS IN THE PLAYPEN SLUMPED OVER HAVING A SEIZURE, FOAM IN HIS MOUTH, CLAMMY, COULD NOT STAND/ WEAKNESS. AN AMBULANCE WAS CALLED, CHILD WAS TAKEN TO THE EMERGENCY ROOM AND RELEASED. EPISODE DIAGNOSED AS A SEIZURE BY THE DOCTOR. CUSTOMER HAD USED THE PRODUCT ON TWO PRIOR OCCASIONS WITH NO PROBLEM.

Received
OCT 05 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.)*

NONE

DSS
OCT 06 2015

(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 N/A

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2 N/A	#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 N/A	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 B00215	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 N/A	#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)

Phone #	Email Address
(b) (6)	

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

OCT – 5 2015

PLEASE TYPE OR USE BLACK INK

☐ 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)*
09/14/15

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 # 1642

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 – 5 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.

DSS

OCT 06 2015

HOMEOPATHIC
MADE IN THE USA SINCE 1903

CaseID: 11603023

SECTION I: **COMPLAINT**

COMPLAINT #: 2652

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 09/14/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABS

LOT NO.: B00215

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT:

ON (b) (6) MOTHER GAVE 2 TABS OF THE PRODUCT AND WITHIN AN HOUR THE CHILD WAS IN THE PLAYPEN SLUMPED OVER HAVING A SEIZURE, FOAM IN HIS MOUTH, CLAMMY, COULDN'T STAND/WEAKNESS. CALLED AN AMBULANCE, CHILD TAKEN TO THE EMERGENCY ROOM AND RELEASED. NOT ADMITTED TO A HOSPITAL. EPISODE DIAGNOSED AS A SEIZURE BY THE DOCTOR. NO TEMPERATURE. CUSTOMER STATED THAT DOCTOR ATTRIBUTED THE SEIZURE TO BELLADONNA IN THE BABY TEETHING TABLETS. HAS USED THE MEDICATION 3 TIMES OVER THE COURSE OF 1.5 WEEKS. CUSTOMER CALLED AND SPOKE WITH THE FDA TODAY AND FILED A REPORT. CUSTOMER WAS UPSET AND STATED THAT SHE THINKS THAT THE PRODUCT SHOULD BE TAKEN OFF THE MARKET BECAUSE IT IS NOT FDA APPROVED. I OFFERED THE CUSTOMER A REFUND AND SHE STATED THAT SHE WOULD LIKE 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)

Individual Case Safety Report

11603023-01-00-03

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**: 09/14/2015

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 #: 1642

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/14/2015 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 09-23-15

BY:
QA / QC DIRECTOR

DATE: 09-23-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

DSS
OCT 06 2015

OCT - 5 2015

Form # VD1

11603023-01-00-04

NDARD
ATHIC
SA SINCE 1903

Iverse Event
SAE-0051-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # B00215, 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 # B00215 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 # B00215. The Baby Teething bulk lot # 126373 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 # B00215.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B00215.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

9/22/2015
Date

CC-0748-2015
AE-0427-2015

DSS
OCT 06 2015

OCT - 5 2015

CaseID: 11603023

11603023-01-00-05

EVENT DATA FORM

AE #: 1642 **COMPLAINT #:** 2652

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: 09-23-15

BY: DATE: 09-23-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

DSS
OCT 06 2015

OCT - 5 2015

Individual Case Safety Report

11614860-01-00-01

user-facilities,
ors and manufacturers
TORY reporting

Form Approved: OMB No. 0910-0291 Expires: 03/30/2015
See OMB statement on reverse.

Case ID: 11614860

NOTE

Mfr Report #

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 ____	☑ 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)*
09/00/2015	09/24/2015

5. Describe Event or Problem

CHILD WAS ADMITTED TO THE HOSPITAL FOR SEIZURES THAT DEVELOPED APPROXIMATELY 1.5 TO 2 WEEKS AGO. WAS ADMITTED AND THEN DISCHARGED HOME AND CONTINUED TO HAVE BREAKTHROUGH SEIZURES. FINALLY HAS STOPPED HAVING SEIZURES DUE TO PHENOBARB USED AS AN ANTICONVULSANT. PARENTS RELATED THAT THEY HAVE BEEN USING THE HYLAND'S BABY TEETHING GEL FREQUENTLY DURING THE TIME THE PATIENT HAS HAD THE SEZIURES. SEIZURE DIAGNOSED AS TONIC CLONIC SEIZURES WITH RIGHT AFFECTING MORE THAN LEFT.

OCT 07 2015

(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.)*

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 GEL

#2

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

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

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 126288	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#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)*

(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 - 8 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)

OCT - 7 2015

Phone #	Email Address
(b) (6)	

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

CaseID: 11614860

11614860-01-00-02

of 5

FDA USE ONLY

1. Check One
☐ User Facility ☐ Importer

2. [illegible]

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)*
09/23/2015

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)
TONIC CLONIC SEIZURES

9. Manufacturer Report Number
54973 AE # 1645

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 - 8 2015

OCT - 7 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.

HOMEOPATHIC
MADE IN THE USA SINCE 1903

Case 14860

SECTION I: **COMPLAINT**

COMPLAINT #: 2655

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 09/23/2015

PRODUCT: HYLAND'S BABY TEETHING GEL

ITEM CODE: TGEL—U0.5Z

SIZE: 0.5 OZ.

LOT NO.: 126288

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT:
DOCTOR STATED THAT 4 MONTH 10 DAY OLD PATIENT WAS ADMITTED TO THE HOSPITAL FOR SEIZURES THAT DEVELOPED APPROXIMATELY 1.5 TO 2 WEEKS AGO. WAS ADMITTED AND THEN DISCHARGED HOME AND CONTINUED TO HAVE BREAKTHROUGH SEIZURES. FINALLY HAS STOPPED HAVING SEIZURES DUE TO PHENOBARB USED AS AN ANTICONVULSANT. PARENTS RELATED THAT THEY HAVE BEEN USING THE HYLAND'S BABY TEETHING GEL FREQUENTLY DURING THE TIME THE PATIENT HAS HAD THE SEZIURES. HE HAS HEARD ABOUT THE RECALL WITH THE TEETHNG TABLETS AND WANTS TO KNOW IF THERE ARE ANY ABNORMALITIES WITH THE TEETHING GEL. SEIZURE DIAGNOSED AS TONIC CLONIC SEIZURES WITH RIGHT AFFECTING MORE THAN LEFT.

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

11614860-01-00-03

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: 09/23/2015

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

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS

OCT - 8 2015

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1645

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/23/2015

BY: EDYTA FRACKIEWICZ

SECTION V:

OCT - 7 2015

REVIEWED BY MANAGEMENT BY: R Wolff

DATE: 10-01-15

BY: Eric Bain
QA / QC DIRECTOR

DATE: 09-30-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

11614860-01-00-04

NDARD PATHIC
USA SINCE 1903

dverse Event
SAE-0054-2015

Product in Inventory:

No units of Hyland's Baby Teething Gel (TGEL), lot #126288, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (b)(4) units, has been distributed.

Review of Records:

The TGEL lot # 126288 was manufactured using bulk lot # 126288. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Certificate of Analysis was reviewed and indicated all results, including Micro, were within specification for Hyland's Baby Teething Gel lot # 126288. 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 two other complaints (CC-0596-2015 & CC-0701-2015) have been received for Hyland's Baby Teething Gel lot # 126288. The complaints were reviewed and they do not appear to be related. SHC will continue to monitor reports for trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Gel lot # 126288.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

9/29/2015
Date

DSS
OCT - 8 201

OCT - 7 2015

11614860-01-00-05

Baxter's 614860

EVENT DATA FORM

AE #: 1645 **COMPLAINT #:** 2655

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

NAME: UNKNOWN

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

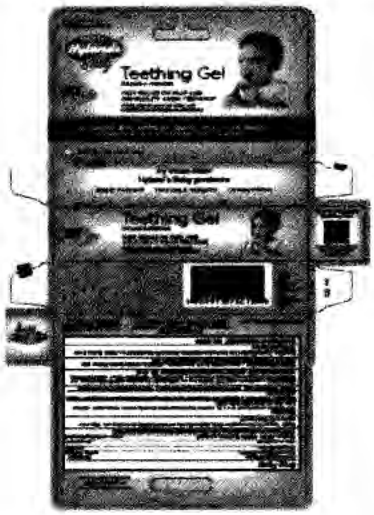
PHONE #:

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
OCT - 8 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-01-15 OCT - 7 2015

BY: Dave Baum DATE: 09-30-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE **FORM SAE01**

Individual Case Safety Report

CaseID: 11614940

11614940-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

by user-facilities,
butors and manufacturers
ATORY reporting

Mfr Report #	
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)	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)*
- ☐ 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)*
03/19/2015	09/28/2015

5. Describe Event or Problem

REPORTER SENT AN E-MAIL THAT ON (b) (6) HER SON HAD 3 PROLONGED SEIZURES. SHE HAD GIVEN HIM SOME OF THE BABY TEETHING TABLETS ON (b) (6) AND A FEW DAYS PRECEEDING. CHILD WAS HOSPITALIZED IN PICU FOR 2 NIGHTS AND 3 DAYS. NO CAUSE FOUND FOR THE SEIZURES FOUND NOR HAS CHILD HAD ANY RECURRENT SEIZURES.

OCT 07 2015

(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	#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
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: ____ *(mm/dd/yyyy)*

OCT - 8 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

OCT - 7 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.

PLEASE TYPE OR USE BLACK INK

11614940-01-00-02

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)*: 09/23/2015
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 # 1646

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 - 8 2015
OCT - 7 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.

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Case ID: 11614940

SECTION I: **COMPLAINT**

COMPLAINT #: 2656

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 09/23/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: NOT PROVIDED

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: (b) (6)

NATURE OF COMPLAINT:

CUSTOMER SENT THE FOLLOWING E-MAIL AND DID NOT RESPOND TO HYLAND'S E-MAIL: HELLO. IF THERE IS AN ACTIVE STUDY GOING ON REGARDING THE HYLAND BABY TEETHING TABLETS AND SEIZURES THEN I NEED TO ADVISE YOU OF MY SON. WHEN MY SON WAS 15 MONTHS OLD ON (b) (6) HE HAD 3 PROLONGED SEIZURES. I HAD GIVEN HIM SOME OF THE TEETHING TABLETS ON (b) (6) AND A FEW DAYS PRECEEDING. WE WERE IN PICU FOR 2 NIGHTS, 3 DAYS. THERE HASN'T BEEN ANY CAUSE FOR THE SEIZURES FOUND NOR HAS HE HAD ANY RECURRENT SEIZURES. PLEASE UPDATE ME ON ANY INFORMATION YOU HAVE REGARDING SEIZURES AND THE TEETHING TABLETS. THANK YOU.

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: 09/23/2015

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

SECTION III: **CORRECTIVE ACTION:**

Individual Case Safety Report

11614940-01-00-03

DSS

DATE: OCT - 8 2015

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1646

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/23/2015 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 10-01-15 OCT - 7 2015

BY: Lynn Bain QA / QC DIRECTOR DATE: 10-01-15

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

Form # VD1

11614940-01-00-04

NDARD PATHIC USA SINCE 1903

Serious Adverse Event
SAE-0055-2015

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-six (136) Adverse Events (AE) which also included fifty-one (51) 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 lots for atropine, scopolamine and *Clostridium botulinum* testing. The total Atropine and Scopolamine levels was found to meet the specification of ≤ (b)(4) ppm and *Clostridium botulinum* testing was negative.

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 — Date: 10/01/15

Reviewed by — Date: 10/1/2015

DSS
OCT - 8 2015

OCT - 7 2015

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hylands 10014940

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1646 **COMPLAINT #:** 2656

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

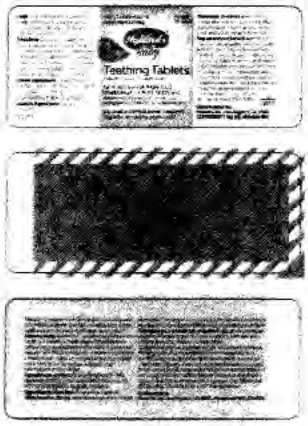
COUNTRY: USA ZIP CODE:

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:**

Individual Case Safety Report

11614940-01-00-05

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
OCT - 8 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Wolf DATE: 10-01-15

BY: Eric Brun DATE: 10-01-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

OCT - 7 2015

CaseID: 11628084

11628084-01-00-01

mer Report

Y reporting of
uct problems and
product use errors

OTC

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit
sequence #
619181

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	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)*
☑ 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)*
09/27/2015	10/09/2015

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: teething tablets and gel Hyland's
Strength: Hylands
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 09/24/2015 - 10/01/2015
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 My 6 month old was 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

OCT 13 2015

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 additional page(s) for complete text.

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

1. Name and Address
(b) (6)

DSS
OCT 13 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

11628084-01-00-02

My 6 month was given both hylands teething tablets and the gel. A few days later she started to displays clusters of a jerking movements at different times throughout the day. After visiting the emergency, her primary doctor, another primary doctor and calling 911 I finally found a hospital with doctors who knew what my daughter was experiencing. She has been experiencing what is known as infantile spasms or west syndrome.

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

My 6 month old was admitted into the hospital on (b) (6) She was given and eeg and diagnosed with infantile spasms on the morning of (b) (6) Later that day (b) (6) (b) (6) she had an MRI which came back normal. It is (b) (6) and we are still in the hospital waiting for blood and urine test results

---

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: None

Allergies: None

Important Information: None

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

RX Meds: Ibuprofen and ACTH therapy for infantile spasms

OTC Meds: None

CaseID: 11639546

Individual Case Safety Report

11639546-01-00-01

...user-facilities, ...ers and manufacturers ...ORY reporting

OTC

Form Approved: OMB No. 0910-0291, Expires: 8/30/2015
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (2/13) Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: CHILD 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)
09/27/2015	10/01/2015

5. Describe Event or Problem

CUSTOMER STATED IN AN E-MAIL THAT CHILD HAS BEEN HAVING SEIZURES SINCE HE HAS BEEN TAKING THE BABY TEETHING TABLETS.

Received
OCT 15 2015
CDR

(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	#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
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
OCT 16 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.

OCT 15 2015

CaseID: 11639546

11639546-01-00-02

FDA USE ONLY

DEVICE MANUFACTURERS 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

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

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)*
09/27/2015

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 # 1648

DSS
OCT 16 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.

OCT 15 2015

CaseID: 11639546

11639546-01-00-03

COMPLAINT #: 2658

DATE OF COMPLAINT: 09/27/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: NOT PROVIDED

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: (b) (6)

NATURE OF COMPLAINT:

CUSTOMER SENT THE FOLLOWING E-MAIL AND DID NOT RESPOND TO HYLAND'S E-MAIL: I WAS WONDERING WHO WOULD SPEAK TO ABOUT YOU GUYS TEETHING TABLETS BECAUSE SUNCE MY SON HAS BEEN TAKEN THEM HIM BEEN HAVING SEIZURES I WILL BE SPEAKING TO A LAWYER MONDAY MORNING ABOUT THIS AND HOW TO TAKE FURTHER PERCUSSION ABOUT THIS MATTER

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**: 09/27/2015

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 #: 1648

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 09/27/2015

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 10-07-15

BY:

QA / QC DIRECTOR

DATE: 10-06-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

OCT 15 2015

11639546-01-00-04

NDARD
PATHIC
ISA SINCE 1903

Serious Adverse Event
SAE-0057-2015

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 fifty-four (54) 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 lots for atropine, scopolamine and *Clostridium botulinum* testing. The total Atropine and Scopolamine levels was found to meet the specification of ≤ (b)(4) ppm and *Clostridium botulinum* testing was negative.

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.

Reviewed by

10/5/15
Date

DSS
OCT 16 2015

OCT 15 2015

11639546-01-00-05

:VENT DATA FORM

AE #: 1648 COMPLAINT #: 2658

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
OCT 16 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-07-15

BY: DATE: 10-06-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

OCT 15 2015

11658849-01-00-01

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

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

OTC

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)
☑ 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): 10/06/2015

4. Date of This Report (mm/dd/yyyy): 10/07/2015

5. Describe Event or Problem

4 MONTH OLD CHILD'S FACE BECAME FLUSHED RED AND CHILD WAS HARDLY BREATHING AFTER TAKING TWO (2)OF THE HYLAND'S TEETHING TABLETS.

RECEIVED
OCT 22 2015
CDR

(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

DSS
OCT 23 2015

(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

#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

54973-3127-3

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)

OCT 22 2015

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

USA

Phone # (b) (6)

Email Address

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

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

CaseID: 11658849

11658849-01-00-02

☐ 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)*
10/06/2015

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)
FLUSHED FACE, DIFFICULTY BREATHING

9. Manufacturer Report Number
54973 AE # 1649

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 22 2015

DSS

OCT 23 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."

CaseID: 11658849

11658849-01-00-03

COMPLAINT #: 2659

DATE OF COMPLAINT: 10/06/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS: REFUSED TO PROVIDE

N/A

CITY: REFUSED TO PROVIDE

STATE: REFUSED TO PROVIDE

COUNTRY: USA

ZIP CODE: REFUSED TO PROVIDE

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER (MOTHER) CALLED TO REPORT HER 4 MONTH OLD CHILD'S FACE BECAME FLUSHED RED AND THAT THE CHILD WAS HARDLY BREATHING AFTER GIVING THE CHILD TWO (2) OF THE HYLAND'S BABY TEETHING TABLETS. MOTHER STATES SHE BROUGHT THE CHILD TO THE HOSPITAL (b) (6) WHERE CHILD WAS ADMITTED FOR FURTHER EVALUATION. WHEN I ASKED HOW THE CHILD WAS DOING, SHE HESITATED, AND DID NOT RESPOND. MOTHER STATES THE CHILD'S DOCTOR TESTED THE TABLETS TODAY AND INFORMED HER THE TABLETS CONTAINED TWICE THE AMOUNT OF BELLADONNA STATED ON THE LABEL.
MOTHER ALSO REPORTS VIEWING A VIDEO POSTED ON THE FDA WEBSITE WHERE THE RISK AND DANGERS OF THE TEETHING TABLETS WERE DISCUSSED. I EXPLAINED THE FDA VIDEO WAS PREPARED AND LAUNCHED IN 2010 DURING THE TIME OF THE RECALL AND THAT IT IS NOT CURRENT INFORMATION. REGARDLESS OF MY EXPLANATION, SHE INSISTED THE VIDEO WAS CURRENT AND THAT THE FDA TESTED THE TEETHING TABLETS LAST MONTH AND FOUND ISSUES WITH IT. CUSTOMER REFUSED TO PROVIDE ANY ADDITIONAL INFORMATION INCLUDING HER ADDRESS, NAME OF CHILD, PRODUCT INFORMATION, NAME OF HOSPITAL, ETC. CUSTOMER STATED I'D HAVE TO OBTAIN THAT INFORMATION FROM HER LAWYERS.
SHE WANTS TO KNOW WHY THE PRODUCT IS STILL ON THE SHELF BEING SOLD AND WANTS TO SPEAK WITH A MEMBER OF OUR LEGAL TEAM OR THE OWNER OF 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 INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/06/2015

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: CATHERINE DOW

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE: OCT 22 2015

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1649

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/06/2015 BY: CATHERINE DOW

DSS OCT 23 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 10-14-15

BY: Eric Bain DATE: 10-09-15
QA / QC DIRECTOR

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

Form # VD1

11658849-01-00-04

NDARD PATHIC
JSA SINCE 1903

Serious Adverse Event
SAE-0058-2015

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 twenty-four (124) Adverse Events (AE) which also included forty-nine (49) 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 lots for atropine, scopolamine and *Clostridium botulinum* testing. The total Atropine and Scopolamine levels was found to meet the specification of ≤ (b)(4) ppm and *Clostridium botulinum* testing was negative.

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.

Reviewed by

10/8/2015
Date

OCT 22 2015

DSS
OCT 23 2015

CaseID: 11658849

11658849-01-00-05

EVENT DATA FORM

AE #: 1649 COMPLAINT #: 2659

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:**

OCT 2 2 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-14-15 DSS

BY: DATE: 10-09-15 OCT 23 2015
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

11683168-01-00-01

Form Approved: OMB No. 0910-0291 Expiration Date: 08/30/2015
See OMB statement on reverse.

CaseID: 11683168

facilities,
nd manufacturers
Y reporting

5

Mfr Report # 5[illegible]3

UF/Importer Report #

FDA Use Only

B. ADVERSE EVENT OR PRODUCT PROBLEM

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

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)*
00/00/2015	10/19/2015

5. **Describe Event or Problem**

CUSTOMER SENT AN E-MAIL STATING THAT SINCE USING THE TABLETS HER CHILD HAS BEEN HAVING SEIZURES.

(Continue on page 3)

6. **Relevant Tests/Laboratory Data, Including Dates**

UNKNOWN

OCT 28 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.)*

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	#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)

OSS

OCT 29 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.

PLEASE TYPE OR USE BLACK INK

CaseID: 11683168

Individual Case Safety Report

FDA USE ONLY

11683168-01-00-02

FORM

F. FO

1. Che
☐ 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

13. Report Sent to Manufacturer? ☐ 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)*

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)*: 10/14/2015

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 # ____

9. Manufacturer Report Number: 54973 AE # 1650

8. Adverse Event Term(s): SEIZURES

ICE MANUFACTURERS ONLY

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 29 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."

STANDARD HOMEOPATHIC

CUSTOMER COMPLAINT RECORD

Case No. 11683168

Individual Case Safety Report

11683168-01-00-03

COMPLAINT #: 2660

DATE OF COMPLAINT: 10/14/2015

ITEM CODE: BTET

SIZE: NOT PROVIDED

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A STATE: N/A

COUNTRY: USA ZIP CODE: N/A

PHONE #: N/A

E-MAIL: (b) (6)

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL AND DID NOT RESPOND TO HYLAND'S REQUEST FOR CONTACT:

SINCE USING THESE TABLETS MY CHILD HAS BEEN HAVING 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 INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/14/2015

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 #: 1650

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/14/2015 BY: EDYTA FRACKIEWICZ

DSS

OCT 29 2015

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 10-20-15

BY: Eric Braun DATE: 10-20-15

QA / QC DIRECTOR

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VD1

Individual Case Safety Report

11683168-01-00-04

STANDARD 1903

vent

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 twenty-five (125) Adverse Events (AE) which also included fifty (50) 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 lots for atropine, scopolamine and *Clostridium botulinum* testing. The total Atropine and Scopolamine levels was found to meet the specification of ≤ (b)(4) ppm and *Clostridium botulinum* testing was negative.

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.

Reviewed by

10/19/2015
Date

DSS
OCT 29 2015

Individual Case Safety Report

11683168-01-00-05

Hyland's 683168

A FORM

AE #: 1650 COMPLAINT #: 2660

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

NAME: (b) (6)

ADDRESS:

CITY: STATE:

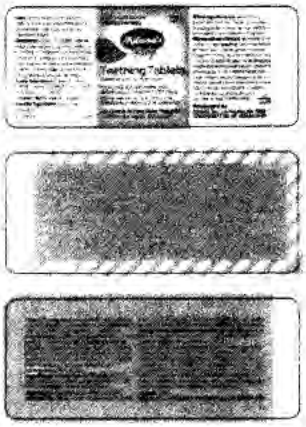
COUNTRY: USA ZIP CODE:

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:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-20-15

DSS
OCT 29 2015

BY: DATE: 10-20-15

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

11699938-01-00-01

user-facilities,
tors and manufacturers
TORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event: 3 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)*: 09/03/2015

4. Date of This Report *(mm/dd/yyyy)*: 10/30/2015

5. Describe Event or Problem

MOTHER REPORTED THAT CHILD WAS BREATHING REALLY WEIRD ON (b) (6) OR (b) (6) AND SHE CALLED 911 AND CHILD WAS TAKEN TO THE HOSPITAL. CHILD WAS UNCONSCIOUS WITH A BREATHING TUBE IN THE HOSPITAL AND SHE HAD SEIZURES. A FOLEY CATHETER WAS ALSO PLACED. WAS HOSPITALIZED FOR ONE WEEK. CURRENTLY CHILD IS ON SEIZURE MEDICATION AND HAS A FOLLOW UP APPOINTMENT WITH A NEUROLOGIST. BABY HAD A FEVER OF 102 DEGREES WHEN THE SEIZURES OCCURRED. HOSPITAL ATTRIBUTED SEIZURES TO THE LEVEL AND QUALITY OF CARE THE CHILD WAS RECEIVING AT HOME.

Received
NOV 03 2015
CDR

(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.)*

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
#1 UNKNOWN
#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
54973-3127-3

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)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

DSS
NOV - 4 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.

NOV - 3 2015

PLEASE TYPE OR USE BLACK INK

11699938-01-00-02

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): 10/30/2015

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, LOSS OF CONSCIOUSNESS

9. Manufacturer Report Number: 54973 AE # 1651

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
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NOV - 3 2015

HOMEOPATHIC
MADE IN THE USA SINCE 1903

CaseID: 11699938

SECTION I: **COMPLAINT**

COMPLAINT #: 2661

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 10/16/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABS

LOT NO.: A76715

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT: WHEN CHILD WAS 3 MOS OLD ON (b) (6) OR (b) (6) SHE WAS BREATHING REALLY WEIRD. MOTHER CALLED 911 AND CHILD TAKEN TO THE HOSPITAL. WHEN SHE GOT TO THE HOSPITAL, SHE HAD SEIZURES. SHE WAS IN THE HOSPITAL FOR A WEEK IN GRAVE CONDITION. DOCTORS PUT IN A BREATHING TUBE AND FOLEY CATHETER. SHE WAS UNCONSCIOUS. CURRENTLY IS ON SEIZURE MEDICATION AND HAS A FOLLOW UP APPOINTMENT WITH NEUROLOGIST. MOTHER WAS USING BABY TEETHING TABLETS AROUND THAT TIME, PUT 2-3 TABS AND UNDER THE TONGUE BID X 2 WEEKS. LAST DOSE WAS 3 DAYS BEFORE THIS EPISODE OCCURRED. BABY HAD A FEVER WHEN THE SEIZURES OCCURRED OF 102 DEGREES. NO FAMILY HISTORY OF SEIZURES. SHE READ INFORMATION ON FACEBOOK THAT BTET TABS CAUSE SEIZURES AND BLEEDING TO THE BRAIN.

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

11699938-01-00-03

DATE REQUESTED PRODUCT BE RETURNED:

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

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/16/2015

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 #: 1651

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/16/2015

BY: EDYTA FRACKIEWICZ

DSS

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 10-27-15

NOV - 4 2015

NOV - 3 2015

BY:

QA / QC DIRECTOR

DATE: 10-26-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

NDARD
PATHIC
USA SINCE 1903

.dverse Event
SAE-0060-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A76715, 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 # A76715 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 # A76715. The Baby Teething bulk lot # 126005 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 # A76715.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A76715.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

10/23/15
Date

DSS
NOV - 4 2015

NOV - 3 2015

CaseID: 11699938

11699938-01-00-05

EVENT DATA FORM

AE #: 1651 COMPLAINT #: 2661

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

NAME: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A STATE: (b) (6)

COUNTRY: USA ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

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: 10-27-15

BY: QA / QC DIRECTOR DATE: 10-26-15

DSS

NOV - 4 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

NOV - 3 2015

Individual Case Safety Report

CaseID: 11700316

11700316-01-00-01

mer Report

Y reporting of
uct problems and
e errors

CDER

Form Approved: OMB No. 0910-0291; Expires: 12/31/2011
See OMB statement on reverse

FDA USE ONLY
Triage unit sequence #
022475

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	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)*
11/02/2015	11/03/2015

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: Hyland's Teething Tablets
Strength:
Manufacturer: Hyland

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	Three times daily	
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 11/01/2015 - 11/02/2015
#2

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

6. Lot #	7. Expiration Date
#1 A91215	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?	8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ 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

2. Common Device Name

3. Manufacturer Name, City and State

CTU
NOV - 4 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)*

See additional page(s) for complete text.

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

1. Name and Address
(b) (6)

DSS
NOV - 4 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

11700316-01-00-02

...me of Problem *(continued)*

Infant started having seizures after taking Hyland Teething tablets.

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

Watch test. Took teething tablets to lab for analysis. They did a urine analysis.

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

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

RX Meds: none

OTC Meds: none

11788548-01-00-01

y user-facilities,
ators and manufacturers
ATORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

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)
- ☐ 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): 05/04/2015

4. Date of This Report (mm/dd/yyyy): 11/06/2015

5. Describe Event or Problem (b) (6)

MOTHER CALLED ABOUT HER CHILD WHO HAD A SEIZURE WHEN HE WAS 1 YEAR OLD. SHE HAD BEEN GIVING HIM BABY TEETHING TABLETS A WEEK PRIOR, AS NEEDED FOR TEETHING. HE HAD NO KNOWN FEVER BEFORE THE SEIZURE. IN ALL, SHE USED 10-15 TABLETS, 1 TABLET PER DOSE. THE SEIZURE OCCURRED IN THE MORNING, AND THE LAST DOSE OF PRODUCT WAS GIVEN THE DAY PRIOR. THE MOTHER WAS RESPONDING TODAY AFTER SHE HEARD ON THE NEWS THAT THERE WAS A POSSIBLE CONNECTION BETWEEN TEETHING TABLETS AND SEIZURE/BRAIN BLEEDS.
THE SEIZURE LASTED 30 MINUTES, WITH JERKING AND EYES ROLLING TO THE BACK OF THE HEAD. THE CHILD WAS UNRESPONSIVE TO HIS NAME. HE WAS TAKEN TO THE LOCAL HOSPITAL FOR 4 HOURS WHERE HE WAS STABILIZED, AND GIVEN ROCEPHIN IM. THEY REFERRED HIM TO THE STATE HOSPTIAL WHERE HE WAS ADMITTED FOR 2 DAYS. A FEVER DEVELOPED AFTER THE SEIZURE, AND HE WAS NOT RELEASED UNTIL IT SUBSIDED. THEY DID BLOOD TESTS, MRI AND CHECKED BRAIN ACTIVITY WHILE ASLEEP AND AWAKE. IT WAS ALL NORMAL. THE CAUSE OF THE SEIZURE WAS NOT DETERMINED. THE MOTHER WAS TOLD TO JUST WATCH HIM. HE WAS NOT TAKING ANY MEDICATION, HAD NO KNOWN ALLERGIES, NOR ANY PRE-EXISTING CONDITIONS. HE HAD HIS LAST IMMUNIZATION AT 9 MONTHS.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

HE WAS TESTED FOR BRAIN ACTIVITY WHILE AWAKE AND ASLEEP; GIVEN BLOOD TESTS, MRI AND XRAYS.

(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

DSS
NOV 27 2015
NOV 30 2015

(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 TAB, AS NEEDED, ORAL
#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
54973-3127-3

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

Received
NOV 27 2015

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
CDR

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)

Phone #
(b) (6)

Email Address

2. Health Professional?
☐ Yes ☑ No

3. Occupation
NA

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

CaseID: 11788548

11788548-01-00-02

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)*
11/06/2015

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 # 1654

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
NOV 30 2015

NOV 27 2015

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Please DO NOT RETURN this form to the above PRA Staff email address.

FORM FDA 3500A (2/13) *(continued)*

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

HE WAS BEING FED ON FORMULA FROM POWDERED MILK. FOLLOW UP VISITS HAVE SHOWN NORMAL RESULTS.

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

CaseID: 11788548

11788548-01-00-04

COMPLAINT #: 2664

DATE OF COMPLAINT: 11/06/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T40

SIZE: 40 TABS

LOT NO.: A74414

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

NATURE OF COMPLAINT: MOTHER CALLED ABOUT HER CHILD WHO HAD A SEIZURE (b) (6) WHEN HE WAS 1 YEAR OLD. SHE HAD BEEN GIVING HIM BABY TEETHING TABLETS A WEEK PRIOR, AS NEEDED FOR TEETHING. HE HAD NO KNOWN FEVER BEFORE THE SEIZURE. IN ALL, SHE USED 10-15 TABLETS, 1 TABLET PER DOSE. THE SEIZURE OCCURRED IN THE MORNING, AND THE LAST DOSE OF PRODUCT WAS GIVEN THE DAY PRIOR. THE MOTHER WAS RESPONDING TODAY AFTER SHE HEARD ON THE NEWS THAT THERE WAS A POSSIBLE CONNECTION BETWEEN TEETHING TABLETS AND SEIZURE/BRAIN BLEEDS.
THE SEIZURE LASTED 30 MINUTES, WITH JERKING AND EYES ROLLING TO THE BACK OF THE HEAD. THE CHILD WAS UNRESPONSIVE TO HIS NAME. HE WAS TAKEN TO THE LOCAL HOSPITAL FOR 4 HOURS WHERE HE WAS STABILIZED, AND GIVEN ROCEPHIN IM. THEY REFERRED HIM TO THE STATE HOSPTIAL WHERE HE WAS ADMITTED FOR 2 DAYS. A FEVER DEVELOPED AFTER THE SEIZURE, AND HE WAS NOT RELEASED UNTIL IT SUBSIDED. THEY DID BLOOD TESTS, MRI AND CHECKED BRAIN ACTIVITY WHILE ASLEEP AND AWAKE. IT WAS ALL NORMAL. THE CAUSE OF THE SEIZURE WAS NOT DETERMINED. THE MOTHER WAS TOLD TO JUST WATCH HIM. HE WAS NOT TAKING ANY MEDICATION, HAD NO KNOWN ALLERGIES, NOR ANY PRE-EXISTING CONDITIONS. HE HAD HIS LAST IMMUNIZATION AT 9 MONTHS. HE WAS BEING FED ON FORMULA FROM POWDERED MILK. FOLLOW UP VISITS HAVE SHOWN NORMAL RESULTS.

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**: 11/06/2015

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

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DSS

NOV 30 2015

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1654

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/06/2015 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 11-17-15

BY:

QA / QC DIRECTOR

DATE: 11-17-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

NOV 27 2015

Form # VD1

11788548-01-00-05

VDARD ATHIC SA SINCE 1903

Serious Adverse Event
SAE-0063-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A74414, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A74414 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 # A74414. The Baby Teething bulk lot # 123797 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 # A74414.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A74414.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

11/13/15
Date

NOV 27 2015

DSS

NOV 30 2015

CC-0935-2015
AE-0527-2015

11788548-01-00-06

EVENT DATA FORM

AE #: 1654 **COMPLAINT #:** 2664

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

NAME: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A STATE: (b) (6)

COUNTRY: USA ZIP CODE: N/A

PHONE #: (b) (6)

E-MAIL: N/A

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: DWalt DATE: 11-17-15

BY: Eric Bean DATE: 11-17-15
QA / QC DIRECTOR

NOV 27 2015

DSS

NOV 30 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

11788578-01-00-01

user-facilities,
tors and manufacturers
TORY reporting

Mfr Report # 54973

UF/Importer Report #

OTC

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: [✓] 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): 00/00/0000

4. Date of This Report (mm/dd/yyyy): 11/12/2015

5. Describe Event or Problem

MOTHER POSTED ON (b) (6) THAT CHILD EXPERIENCED BELLADONNA POISONING AND SEIZURES AFTER THE USE OF BABY TEETHING TABLETS. CHILD NOW HAS TO BE SEEN BY NEUROLOGISTS AND REQUIRES MEDICAL CARE.

(Continue on page 3)

Received
NOV 27 2015
CDR

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

DSS
NOV 30 2015
NOV 27 2015

(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 TAB TID X 1 DAY
#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
54973-3127-3

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)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

USA

Phone #

Email Address
(b) (6)

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

3. Occupation: NA

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

CaseID: 11788578

11788578-01-00-02

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)*: 11/06/2015

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): BELLADONNA POISONING, SEIZURES

9. Manufacturer Report Number: 54973 AE # 1655

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 30 2015

NOV 27 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.

CaseID: 11788578

11788578-01-00-03

COMPLAINT #: 2665

DATE OF COMPLAINT: 11/06/2015

ITEM CODE: BTET---T40

SIZE: 40 TABS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: (b) (6)

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (b) (6) AND WOULD NOT CALL HYLAND'S AFTER SEVERAL REQUESTS: DEAR HYLANDS TEETHING TABLETS IM A FIRST TIME AND HAVE A 10 MONTH OLD DAUGHTER. THINKING YOUR PRODUCT WAS SAFE LANDED MY DAUGHTER IN THE HOSPITAL ER. WE HAD A VERY FRIGHTFUL NIGHT THAT ENDED IN AN ER VISIT MANY SLEEPLESS NIGHTS DUE TO POSIONING FROM YOUR TEETHING TABLETS. THE DOCTOR SAID HE WAS AMAZED THAT YOUR PRODUCT IS LABELED SAFE SINCE BELLADONNA IS STILL IN IT. NOTHING CAN REPLACE THE DAYS I SPENT WITH DAUGHTER SEIZING UP FROM YOUR TABLETS. THE FEAR HER FATHER AND I WENT THROUGH. AS A MOM I WILL NEVER TOUCH YOUR PRODUCT AGAIN AND HAVE ALSO BEEN IN CONTACT WITH THE FDA AND POSION CONTROL SINCE SHE COULD HAVE DIED. PLEASE BE HONEST AND ADMIT THE TRUTH BEHIND BELLADONNA AN ACTIVE INGREDIENT WHICH IS MADE FROM THE DEATHLY PLANT KNOW. AS NIGHTSHADE. IT IS SAD PARENTS THINK FALLING ASLEEP INSTANTLY OR THE LITTLE SMALL THINGS ARE TEETHING RELATED AND USE YOUR PRODUCT WHEN ITS THE PRODUCT ITSELF CAUSING PROBLEMS. IM LUCKY ENOUGH TO SAY MY DAUGHTER SHOULD BE ALRIGHT BUT NOW HAS TO SEE NEUROLOGISTS AND MY EXPENSE BECAUSE I READ THE WORD SAFE ON YOUR PRODUCT LABEL AND ONLY 3 TABLETS INTO THE BOTTLE LANDED MY DAUGHTER IN THE HOSPITAL. PS THEY CHECKED HER FOR EVERYTHING AND IT WAS BELLADONNA POISONING. AFTER THE DIAGNOSIS WE STARTED TO DIG AND FOUND THE FDA HAS A VIDEO OUT URGING PARENTS THIS COULD HAPPEN TO THEIR KIDS. ALSO SENT THE FOLLOWING E-MAILS #1: I RECENTLY PURCHASED A BOTTLE OF 125 COUNT FROM FAMILY DOLLAR AND MY DAUGHTER EXPERIENCED SEIZURES SHORTLY AFTER THE THREE TABLETS I GAVE HER ALL THREE WERE GIVEN AT SEPARATE TIMES OVER A 24 HR PERIOD. WE HAVE DOCUMENTATION SHE SUFFERED FROM SEIZURES FROM THE BELLADONNA. IN YOUR PRODUCT WHAT DO YOU PLAN ON DOING TO PREVENT THIS. #2 A REFUND WONT PAY FOR THE BILLS WE HAVE NOW BECAUSE OF THE POSIONING. OR GET THE NEWS OUT THERE YOUR PRODUCT ISNT SAFE. I HAVE ALREADY STARTED MEETING WTH AN ATTORNEY REGUARDING THIS PROBLEM SINCE MY DAUGHTER NOW REQUIRES MEDICAL CARE. I ALREADY KNOW ABOUT BELLADONNA THANKS TO POSION CONTROL AND THE FDA I WAS FORCED TO MEET WITH AFTER ONLY 3 TABLETS OF 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 INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 11/06/2015

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 #: 1655

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/06/2015 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: Result DATE: 11-17-15

BY: Eric Bain QA / QC DIRECTOR DATE: 11-17-15

NOV 27 2015

DSS

NOV 30 2015

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

11788578-01-00-04

VDARD ATHIC IA SINCE 1903

Serious Adverse Event
SAE-0064-2015

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 and three (103) Adverse Events (AE) which also included forty-seven (47) 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 lots for atropine, scopolamine and *Clostridium botulinum* testing. The total Atropine and Scopolamine levels was found to meet the specification of ≤ (b)(4) ppm and *Clostridium botulinum* testing was negative.

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.

Reviewed by

11/13/15
Date

NOV 2 7 2015

CC-0952-2015
AE-0537-2015

DSS
NOV 30 2015

DSS
NOV 30 2015

11788578-01-00-05

VT DATA FORM

AE #: 1655 **COMPLAINT #:** 2665

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

NAME: (b) (6)

ADDRESS: N/A

N/A

CITY: N/A STATE: N/A

COUNTRY: N/A ZIP CODE: N/A

PHONE #: N/A

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:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11-17-15

BY: QA / QC DIRECTOR DATE: 11-17-15

NOV 27 2015

DSS

NOV 30 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

11878433-01-00-01

CaseID: 11878433

mer Report

Y reporting of
ict problems and
e errors

CDER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence #

630318

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	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)*
12/28/2015	12/28/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) 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 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: hylands teething tablets
Strength: unknown
Manufacturer: hylands

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 tablets	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 12/02/2015 - 12/28/2015	#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	#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	54973-3127-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU
DEC 29 2015

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 29 201

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

11878433-01-00-02

ive been giving my son hylands teething tablets for about a month now and hes been sleeping alot, being constipated. is this a serious problem

---

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)*

Race: American Indian/Alaskan Native

Medical Conditions:

Allergies:

Important Information:

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

Individual case safety report

11999660-01-00-01

CaseID: 11999660

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

...Y reporting of
...uct problems and
...e errors

Adverse Event Reporting Program

Page 1 of 2

FDA USE ONLY
Triage unit sequence # 6360165

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event or Date of Birth: (b) (6)
3. Sex: ☐ Female ☑ Male
4. Weight: unknown lb or unknown 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 unknown
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 9/9/15 9/10/15
4. Date of this Report (mm/dd/yyyy): JAN 2016

5. Describe Event, Problem or Product Use Error
child has seizure falling on head. child continued to have seizures, cause is Hylands Teething Tablets

6. Relevant Tests/Laboratory Data, Including Dates
See med reports

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
no preexisting med 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: Hylands teething Tablets
Strength: see lot # above
Manufacturer:
#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 See below		mouth
#2 use as directed		

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

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

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

6. Lot #
#1 B408141
#2 A68015

7. Expiration Date
#1 unk
#2 unk

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: Hylands teething Tablets
2. Common Device Name:
2b. Procode:
3. Manufacturer Name, City and State: Hylands Inc Los Angeles Calif. 90061
4. Model #: See above
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

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 #: (b) (6)
E-mail: (b) (6) (b) (6)
2. Health Professional? ☐ Yes ☑ No
3. Occupation: Mom
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: ☐

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.

CaseID: 11999660

LAW OFFICES

(b) (6)

(b) (6)

(b) (6)

0361165 OTC

Individual Case Safety Report

11999660-01-00-02

January 25, 2016

MedWatch
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852-9787

CTU
FEB - 3 2016

RE: Party Name: (b) (6)
Party Date of Incident:

Dear Sir or Madam:

Enclosed please find Form FDA 3500 (2/13) which has been completed on behalf of my client in regards to injuries sustained on (b) (6) from the use of the product "Hyland's Teething Tablets." Should you have any questions, please give Attorney (b) (6) a call at (b) (6) to discuss this matter further. With kindest regards, I am

Very truly yours

(b) (6)

(b) (6)

Enclosure: Form FDA 3500 (2/13)

DSS
FEB 03 2016

Individual Case Safety Report

CaseID 12009242

12009242-01-00-01

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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 #
636371

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	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)*
01/31/2016	02/03/2016

5. Describe Event, Problem or Product Use Error

See additional page(s) 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 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: Hyland's Baby Teeting Tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 tablets	As needed	Taken by mouth
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 01/31/2016 - 01/31/2016
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 To help relieve pain due to 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 B01415	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU
FEB - 4 2016

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: ☐

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.

DSS
FEB 04 2016

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

Administered Hyland's Teething Tablets (2 tablets, recommended dosage) to infant baby at 7:30pm. Infant weighs 19lbs. At 10:00pm infant experienced excessive vomiting, nausea, and labored breathing. No other variables were introduced that day. Infant is exclusively breastfed. Symptoms lasted approximately 30 minutes, no reoccurrence afterward.

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)*

Race: White

Medical Conditions:

Allergies:

Important Information:

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

Individual Case Safety Report

12009242-01-00-02

12079943-01-00-01

ARY reporting of
product problems and
t use errors

1 of 1

CTLR

Case ID: 12079943

FDA USE ONLY

Triage unit sequence # 192612

011610 637915

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
In confidence	9 mos	☐ 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)*
	01/08/2016

5. Describe Event, Problem or Product Use Error

Nine month old son was healthy and up-to-date on shots and doctor visits at the time. Son is teething and parents gave him Hylands Teething Tablets as recommended by a family member. Son was given two tablets and within three hours later he had experienced a seizure. He was unresponsive, parents dialed 911, and child was taken to the ER. He improved and was not admitted to hospital. Doctor ran tests and found nothing. Father is concerned that his son's seizure is related to bella donna in product. He cites youtube video of a NIH case study by the FDA. Son has twin sister & parents monitor all new food introduced to kids for any possible allergic reactions.

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.)*

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

#2

2. Dose or Amount	Frequency	Route
#1		
#2		

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

#1

#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

#2

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

FEB 12 2016

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 # (b) (6)

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

FORM FDA 3500 (10/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FEB 12 2016

12197698-01-00-01

CaseID: 12197698

Report

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product use errors

ORDER

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 #

644637

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	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)* ☐ 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)*
03/17/2016	03/19/2016

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: Hyland teething tablets
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer: DSS

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 03/16/2016 - 03/17/2016
#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

MAR 21 2016

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:

US

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

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.

MAR 21 2016

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

Gave infant low dose Hyland teething tablets, took to doctor where blood tests confirmed mild dehydration. No other drugs were administered and baby was in good health prior. Baby was eating expressed breastmilk normally. No change in diet.

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

Blood panel showed mild dehydration

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:

Allergies:

Important Information:

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

Individual Case Safety Report

12197698-01-00-02

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12470569-01-00-01

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Form Approved: OMB No. 0910-0291, Expires: 09/30/2018
See PRA statement on reverse.

CaseID 12470569

FDA USE ONLY

Triage unit sequence #	662552
FDA Rec. Date	

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)

In Confidence

2. Age: 16 ☐ Year(s) ☑ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth *(e.g., 08 Feb 1925)*

3. Sex: ☑ Female ☐ Male

4. Weight: 25 ☑ lb ☐ kg

5.a. Ethnicity *(Check single best answer)*
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. Race *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☑ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

2. Outcome Attributed to Adverse Event *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* _____
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects
☑ Other Serious (Important Medical Events) Shaking
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(dd-mmm-yyyy)*	4. Date of this Report *(dd-mmm-yyyy)*
11-Jun-2016	14-Jun-2016

5. Describe Event, Problem or Product Use Error
See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

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

#1 - Name and Strength: Hylands baby teething tablets	#1 - NDC # or Unique ID
#1 - Manufacturer/Compounder: Hylands Inc.	#1- Lot #: A15116
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2- Lot #

DSS

JUN 15 2016

3.	Dose or Amount	Frequency	Route
#1	135 Tablet(s)	Every 6 hours	Taken by mouth
#2			

4. Dates of Use *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 08-Jun-2016 - 11-Jun-2016
#2

5. Diagnosis or Reason for Use *(indication)*
#1 Teething
#2

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☑ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. Expiration Date *(dd-mmm-yyyy)* #1 #2

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

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU
JUN 15 2016

2. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(dd-mmm-yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(dd-mmm-yyyy)* | 7. If Explanted, Give Date *(dd-mmm-yyyy)*

8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

9. If Yes to Item 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)

Country: US | ZIP/Postal Code (b) (6)

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

2. Health Professional? ☐ Yes ☐ No

3. Occupation

4. Also Reported to:
☐ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (10/15) 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)*

We gave our daughter hylands teething tablets as directed and she is 16 months old and weighs about 25lbs and we noticed her shaking,like a really bad tremble, and it gradually wore off over the next few hours, she slept almost all day for 2 days after that, and I just read online that kids had seizures from it so I wanna get her checked out now,so scheduling an appointment. Just wanted to let someone know because we don't want any other parents to see that, it scared me at first yanno?

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

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

Medical Conditions: None

Allergies: None

Important Information: Healthy baby

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

RX Meds: None

OTC Meds: Tylenol,motrin,alternating every 8 hours

Individual Case Safety Report

12470569-01-00-02

CaseID: 12480346

12480346-01-00-01

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errors

Form Approved: OMB No. 0910-0291, Expires: 09/30/2018
See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date 6663302

1/2

The FDA Safety Information and Adverse Event Reporting Program

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6) In Confidence

2. **Age** 9 ☐ Year(s) ☑ Month(s) ☐ Week(s) ☐ Day(s) or Date of Birth *(e.g., 08 Feb 1925)*

3. **Sex** ☐ Female ☑ Male

4. **Weight** 21 ☑ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☑ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* _____
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects
☑ Other Serious (Important Medical Events) seizure, muscle weakness
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)* 04-May-2016

4. **Date of this Report** *(dd-mmm-yyyy)* 16-Jun-2016

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, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

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

#1 - Name and Strength	#1 - NDC # or Unique ID
Hylands Teething Tablets	
#1 - Manufacturer/Compounder	**#1- Lot #**
Hylands	
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

3. Dose or Amount	Frequency	Route
#1	As Needed	Taken by mouth
#2		

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 01-Apr-2016 - 26-May-2016
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 for Teething
#2

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

10. **Event Reappeared After Reintroduction?**
#1 ☑ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☐ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 30-Jun-2016 #2

E. SUSPECT MEDICAL DEVICE

1. **Brand Name** CTU

2. **Common Device Name** JUN 17 2016 **2b. Procode**

3. **Manufacturer Name, City and State**

4. **Model #** **Lot #** **5. Operator of Device**
☐ Health Professional ☐ Lay User/Patient ☐ Other

Catalog # **Expiration Date** *(dd-mmm-yyyy)*

Serial # **Unique Identifier (UDI) #**

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* **7. If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 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)

Country: US ZIP/Postal Code: (b) (6)

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

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:**
☐ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☑

DSS JUN 17 2016

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (10/15) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

12480346-01-00-02

The baby sitter gave my 8 month old Hyland's teething tablets and he suddenly had muscle weakness and fell into a deep sleep. She had to wake the baby up by rubbing his chest and placed cold water on his face to get him to wake up.

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

I took my 8 month old to his pediatrician. She read the ingredients on the bottle and immediately advised me to throw them away.

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

Medical Conditions: healthy baby boy

Allergies: none

Important Information: none

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

RX Meds: none

OTC Meds: Children's Tylenol

U.S.

12491395-01-00-01

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CaseID: 12491395

FDA USE ONLY

Triage unit sequence #	
FDA Rec. Date	06/21/20

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6)

In Confidence

2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth *(e.g., 08 Feb 1925)* (b) (6)

3. **Sex** ☑ Female ☐ Male

4. **Weight** 16 ☑ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☑ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

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

3. **Date of Event** *(dd-mmm-yyyy)*: 17-Mar-2016

4. **Date of this Report** *(dd-mmm-yyyy)*: 21-Jun-2016

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, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

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

#1 - Name and Strength	#1 - NDC # or Unique ID
Teething Tablets	
#1 - Manufacturer/Compounder	**#1- Lot #**
Hylands Baby	B51615
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

3. **Dose or Amount** / **Frequency** / **Route**

	Dose or Amount	Frequency	Route
#1	2 Tablet(s)	--	Taken by mouth
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 01-Mar-2016 - 17-Apr-2016
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 She is teething and I used to to help calm her and ease pain
#2

6. **Is the Product Compounded?** #1 ☐ Yes ☑ No #2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?** #1 ☑ Yes ☐ No #2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 #2

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

10. **Event Reappeared After Reintroduction?** #1 ☐ Yes ☐ No ☑ Doesn't apply #2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

CTU
JUN 22 2016

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** *(dd-mmm-yyyy)*

Serial # / **Unique Identifier (UDI) #**

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

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 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
JUN 22 2016

Country: US / ZIP/Postal Code: (b) (6)

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

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:** ☐ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☑

PLEASE TYPE OR USE BLACK INK

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

My daughter took Hylands teething tabs (2 tablets that morning) and had a seizure in the evening. She was 5 months old at the time and was WAY under the maximum dose. She consumed a total of 4 tablets in 24 hours. 2 tablets the previous and and 2 tablets the morning of the seizure. We brought her to children's hospital and she was admitted and they did and EEG and found nothing wrong with our little girl.

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

Normal growth and development evaluation and an EEG

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

Medical Conditions: No other medications. The dates listed here are Estimated. I do not know hospitalization date at the top of my head.

Allergies: No known allergies.

Important Information: None

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

RX Meds: None

OTC Meds: None

Individual Case Safety Report

12491395-01-00-02

Individual Case Safety Report

12606520-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 09/30/2018
See PRA statement on reverse.

CaseID: 12606520

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FDA USE ONLY	
Triage unit sequence #	706639
FDA Rec. Date	

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6)
In Confidence

2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)
or Date of Birth *(e.g., 08 Feb 1925)* (b) (6)

3. **Sex** ☐ Female ☑ Male

4. **Weight** 18.15 ☑ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☑ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

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

3. **Date of Event** *(dd-mmm-yyyy)*: 23-Jul-2016

4. **Date of this Report** *(dd-mmm-yyyy)*: 27-Jul-2016

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, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

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

#1 - Name and Strength	#1 - NDC # or Unique ID
Hylands Teething Tablets	
#1 - Manufacturer/Compounder	**#1- Lot #**
Hylands	
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

3.

	Dose or Amount	Frequency	Route
#1	2 Tablet(s)	Once a day	Taken by mouth
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 23-Jul-2016 - 23-Jul-2016
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 Teething
#2

6. **Is the Product Compounded?**
#1 ☐ Yes ☑ No
#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**
#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 #2

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

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** 2b. **Procode**

3. **Manufacturer Name, City and State**

CTV JUL 28 2016

4. **Model #** **Lot #**

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

Catalog # **Expiration Date** *(dd-mmm-yyyy)*

Serial # **Unique Identifier (UDI) #**

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* 7. **If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 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 JUL 28 2016

Country: US ZIP/Postal Code (b) (6)

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

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:**
☐ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

PLEASE TYPE OR USE BLACK INK

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

Gave 6 month old son 2 Hylands Teething Tablets aprox 6:30pm (b) (6) Within (b) (6) began to notice odd behavior. Baby is normally crawling and playing with good coordination and just fell over. Started acting drunk, delirious and very uncoordinated. Went to the ER and symptoms correlated with belladonna poisoning. Symptoms have continued for four days. He is getting better but not back to normal. He is continuing to act spacey and exhausted with bursts of strange euphoria. He is very tired but also restless at the same time. Went to the ER a second time and blood work was done. Doctors opinion was the ingredients in the teething tablets were still effecting him.

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

(b) (6) blood work done at (b) (6) medical center

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

Medical Conditions: None

Allergies: None known

Important Information:

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

RX Meds: None

OTC Meds:

Individual Case Safety Report

12654615-01-00-01

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Form Approved: OMB No. 0910-0291, Expires: 09/30/2018 See PRA statement on reverse.

CaseID: 12654615

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date 074018

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6)

In Confidence

2. **Age** 5 ☐ Year(s) ☑ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth *(e.g., 08 Feb 1925)*

3. **Sex** ☐ Female ☑ Male

4. **Weight** 18 ☑ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*

☐ Hispanic/Latino

☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*

☐ Asian ☐ American Indian or Alaskan Native

☑ Black or African American ☐ White

☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**

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

☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

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

☐ Death *Include date (dd-mmm-yyyy):* _____

☐ Life-threatening

☑ Hospitalization - initial or prolonged

☑ Other Serious (Important Medical Events) Seizures

☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

☑ Disability or Permanent Damage

☐ Congenital Anomaly/Birth Defects

3. **Date of Event** *(dd-mmm-yyyy)* 01-Aug-2016

4. **Date of this Report** *(dd-mmm-yyyy)* 13-Aug-2016

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, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

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

#1 - Name and Strength	#1 - NDC # or Unique ID
Hyland's Baby Teething Tablets	
#1 - Manufacturer/Compounder	**#1- Lot #**
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**
DSS AUG 15 2016	

3.	Dose or Amount	Frequency	Route
#1		--	--
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*

#1

#2

5. **Diagnosis or Reason for Use** *(indication)*

#1 The baby was Teething

#2

9. **Event Abated After Use Stopped or Dose Reduced?**

#1 ☑ Yes ☐ No ☐ Doesn't apply

#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**

#1 ☑ Yes ☐ No ☐ Doesn't apply

#2 ☐ Yes ☐ No ☐ Doesn't apply

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☑ Yes ☐ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 #2

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** CTU

2b. **Procode**

3. **Manufacturer Name, City and State** AUG 15 2016

4. **Model #**

Lot #

5. **Operator of Device**

☐ Health Professional

☐ Lay User/Patient

☐ Other: _____

Catalog #

Expiration Date *(dd-mmm-yyyy)*

Serial #

Unique Identifier (UDI) #

6. **If Implanted, Give Date** *(dd-mmm-yyyy)*

7. **If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 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)

Country: US ZIP/Postal Code: (b) (6)

Phone #: (b) (6)

E-mail: (b) (6)

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:**

☐ Manufacturer/ Compounder

☐ User Facility

☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

PLEASE TYPE OR USE BLACK INK

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

I started giving my baby Hyland's Baby Teething Tablet 2 weeks after he turned 4 months. (b) (6) he had multiple seizures and I took him straight to the Children's Hospital. He had a EEG done for 48 hours, a MRI, and a Spinal Tap. Everything came back normal. He was in the hospital for a week and was not taking the teething medicine. During that week I haven't noticed any more seizures until August 12 when I gave him the teething medicine again. An hour after I gave him the medicine he had 2 seizures.

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

He received the Spinal Tap, EEG and MRI.

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

Medical Conditions:

Allergies:

Important Information:

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

Individual Case Safety Report

12654615-01-00-02

U.S. Individual Case Safety Report

12689440-01-00-01

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FDA USE ONLY

Triage unit sequence #

FDA Rec. Date 675892

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6)

In Confidence

2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth *(e.g., 08 Feb 1925)* (b) (6)

3. **Sex** ☑ Female ☐ Male

4. **Weight** 19 ☑ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*

☐ Hispanic/Latino

☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*

☐ Asian ☐ American Indian or Alaskan Native

☐ Black or African American ☑ White

☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**

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

☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

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

☐ Death *Include date (dd-mmm-yyyy):* _____

☐ Life-threatening ☐ Disability or Permanent Damage

☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects

☐ Other Serious (Important Medical Events)

☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)*: 23-Aug-2016

4. **Date of this Report** *(dd-mmm-yyyy)*: 24-Aug-2016

5. **Describe Event, Problem or Product Use Error**

See additional page(s) for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**

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

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

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

#1 - Name and Strength: Hyland's Teething Tablets	#1 - NDC # or Unique ID: 54973-3127-1
#1 - Manufacturer/Compounder: Hyland's	#1- Lot #: B70415
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2- Lot #

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3. **Dose or Amount** / **Frequency** / **Route**

	Dose or Amount	Frequency	Route
#1	2 Tablet(s)	As Needed	Taken by mouth
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*

#1 15-Aug-2016 – 23-Aug-2016

#2

5. **Diagnosis or Reason for Use** *(indication)*

#1 Teething pain

#2

6. **Is the Product Compounded?**

#1 ☐ Yes ☑ No

#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**

#1 ☑ Yes ☐ No

#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 #2

9. **Event Abated After Use Stopped or Dose Reduced?**

#1 ☑ Yes ☐ No ☐ Doesn't apply

#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**

#1 ☐ Yes ☐ No ☑ Doesn't apply

#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** CTU

2b. **Procode**

3. **Manufacturer Name, City and State** AUG 25 2016

4. **Model #**

Lot #

5. **Operator of Device**

☐ Health Professional

☐ Lay User/Patient

☐ Other: _____

Catalog #

Expiration Date *(dd-mmm-yyyy)*

Serial #

Unique Identifier (UDI) #

6. **If Implanted, Give Date** *(dd-mmm-yyyy)*

7. **If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 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)

Country: US ZIP/Postal Code: (b) (6)

Phone #: (b) (6)

E-mail: (b) (6)

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:**

☑ Manufacturer/ Compounder

☐ User Facility

☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

PLEASE TYPE OR USE BLACK INK

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

My daughter is nine months old and experienced symptoms after consuming Hyland's teething tablets. I had been giving her two tablets a day for about five days when I noticed it for the first time. She would suddenly drop her head down and have trouble lifting it back up. She had several episodes, most severely about an hour or two after taking the dose of tablets. She also experienced extreme thirst during/after these episodes and would drink more water or milk in a few hours than she normally drinks most of the day. I now have discovered that these events are tied to the teething tablets and I think it may be an adverse reaction to the belladonna in the tablets. She was getting much less than the recommended daily dose and still had a reaction.

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

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

Medical Conditions: None

Allergies: None

Important Information: None

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

RX Meds: None

OTC Meds: Infant Motrin Concentrated drops (1.25mL, rare occasions) Infant Tylenol (2.5 mL, only when fever is high)

12693124-01-00-01

CDER

reporting of
problems and
errors

OTC

Form Approved: OMB No. 0910-0291, Expires: 09/30/2018

CaseID: 12693124

FDA USE ONLY

Triage unit sequence # 676113

FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6) In Confidence

2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth *(e.g., 08 Feb 1925)* (b) (6)

3. **Sex** ☑ Female ☐ Male

4. **Weight** 11.3 ☐ lb ☑ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☑ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* _____
☐ Life-threatening
☑ Hospitalization - initial or prolonged
☑ Other Serious (Important Medical Events) Seizures
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

3. **Date of Event** *(dd-mmm-yyyy)*: 24-Aug-2016

4. **Date of this Report** *(dd-mmm-yyyy)*: 25-Aug-2016

5. **Describe Event, Problem or Product Use Error**
See additional page(s) for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

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

#1 - Name and Strength	#1 - NDC # or Unique ID
Hyland's Baby Teething Tablets	54973-3127-1
#1 - Manufacturer/Compounder	**#1- Lot #**
Hyland's	A60714
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2- Lot #

3. **Dose or Amount** / **Frequency** / **Route**

	Dose or Amount	Frequency	Route
#1	3 Tablet(s)	Four times a day	Taken by mouth
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 6 Months
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 To soothe infant teething pain
#2

6. **Is the Product Compounded?**
#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**
#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 #2

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

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** 2b. **Procode**

3. **Manufacturer Name, City and State**

4. **Model #** **Lot #**

Catalog # **Expiration Date** *(dd-mmm-yyyy)*

Serial # **Unique Identifier (UDI) #**

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

6. **If Implanted, Give Date** *(dd-mmm-yyyy)*

7. **If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 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)

Country: US ZIP/Postal Code (b) (6)

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

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:**
☐ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (10/15) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

CTU AUG 26 2016

DSS AUG 26 2016

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

My 15 month old took 3 teething tabs (as directed) and 30 min later had a seizure. (b) (6)
after that had a second seizure and required sedation and hospitalization.

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

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

Medical Conditions: None

Allergies: None

Important Information: None, very healthy

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

RX Meds: None

OTC Meds: None

Individual Case Safety Report

12693124-01-00-02

DSS
AUG 26 2016

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	**Originating Account**	FAERS
Source Medium	MWO (Drug)	**Source Form Type**	E2B XML 3500B
Priority	Routine		
FDA Received Date	03-Sep-2016	**CTU Received Date**	03-Sep-2016 19:45:05
Report Type	Spontaneous	**Report Classification**	
Assign To	User		
User/Group			
Forward to Department	☑ CDER		

Contact

Source Form Type	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ 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 ☑ Other serious/important medical incident
Date of Death	
Other serious/important medical incident	Severe urticaria in infant
Date the problem occurred	27-Aug-2016

Tell us what happened and how it happened (Include as many details as possible)

My child presented with severe urticaria (b) (6) after he was given baby orajel for 3 days as directed. My child still has severe urticaria and is being treated with prednisolone once a day and Benadryl every four hours.

List any relevant tests or laboratory data if you know them (Include dates)

Blood tests, cbc, pt, ptt,

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Orajel Teething swabs		
Name of the company that makes (or compounds) the product	Church & Dwight		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date	01-Nov-2018		
Lot number	Gp6006		
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)	7.5 % percent	**If Other**	
Quantity	1 Other	**If Other**	
Frequency	4 times a day	**If Other**	
How was it taken or used	Topical		
Date the person first started taking or using the product	17-Aug-2016		
Date the person stopped taking or using the product	19-Aug-2016		
Did the problem stop after the person reduced the dose or stopped taking or using the	No		

product?	
Did the problem return if the person started taking or using the product again?	Doesn't Apply
Do you still have the product in case we need to evaluate it?	Yes

Why was the person using the product? (such as what condition was it supposed to treat)

Teething

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Male
Age (specify unit of time for age)	5 Month(s)
Date of Birth	
Weight	7.2 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

None

Please list all allergies (such as to drugs, foods, pollen or others)

None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

None

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	
Number/Street	
City	
State/Province	
Country	
ZIP or Postal code	
Telephone number	
Email address	
Today's date	03-Sep-2016
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐

Message Subject :
Received Time : Fri Sep 02 08:38:21 EDT 2016
Sender Address : ylaci.duke@fda.hhs.gov
TO Addresses : CDER-CTU-Scan@fda.hhs.gov; ylaci.duke@fda.hhs.gov;
CC Addresses :
No. of Inline/ Attachments : 1
DUKEY_090216_083530.pdf

Message content follows :

Internet Consumer Report

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Form Approved: OMB No. 0910-0291 Expires: 09/30/2018
See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6)

In Confidence

2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth *(e.g., 08 Feb 1925)* (b) (6)

3. **Sex** ☑ Female ☐ Male

4. **Weight** 19 ☑ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☑ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

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

3. **Date of Event** *(dd-mmm-yyyy)*: 19-Aug-2016

4. **Date of this Report** *(dd-mmm-yyyy)*: 01-Sep-2016

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, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

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

#1 - Name and Strength	#1 - NDC # or Unique ID
Infant Teething Tablets	59779-860-03
#1 - Manufacturer/Compounder	**#1- Lot #**
Homelab Inc (Canada)	41116
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2- Lot #

3. **Dose or Amount** / **Frequency** / **Route**

	Dose or Amount	Frequency	Route
#1	3 Tablet(s)	Every 6 hours	Taken by mouth
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 17-Aug-2016 - 18-Aug-2016
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 Teething
#2

6. **Is the Product Compounded?**
#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**
#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 31-Mar-2018 #2

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

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** / 2b. **Procode**

3. **Manufacturer Name, City and State**

4. **Model #** / **Lot #** / **Catalog #** / **Expiration Date** *(dd-mmm-yyyy)* / **Serial #** / **Unique Identifier (UDI) #**

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

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

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 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)

Country: US ZIP/Postal Code: (b) (6)

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

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:**
☑ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

PLEASE TYPE OR USE BLACK INK

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

On (b) (6) My daughter (b) (6) had to be rushed to (b) (6) Hospital . She was seizing for approximately 25 minutes, she was unresponsive, cyanotic and gasping for air, upon arrival EMS gave her diazepam IM and she continued to seize while going to the hospital. Diagnosis at the emergency room was Status Epilepticus. The only new Item that was introduced to (b) (6) was the CVS brand Homeopathic theeting tablets. Upon inspection at the emergency room , it was discovered that the CVS pills contained Belladona . Belladona is a highly toxic substance that was once used to poison people. Although the percentagage of Belladona per the label is 0000000003%. There has been no significant clinical testing to verifythat this product is safe for children from 0-3 years of age, as is shown on the label of the CVS product. I have been in touch with CVS , regarding the issue and they referred me to the Manufacturer of the product. The CVS representative stated that they market the product only. The representative also stated that the ingredients of the product are imported from China . As a member of the Law Enforcemnt community , I believe that this product should be inspected to make sure that it is safe for human consumption especially for children .It also states on the box that the ingredients are forgein sources V-30496

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

I will send lab results upon request

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

Medical Conditions: No Known Medical Problems, Baby has never been sick or inside a hospital since she was born.

Allergies: No Known drug allergies

Important Information: N/A

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

RX Meds: None

OTC Meds: CVS Homeopathic Infants Teething Tablets , No other medication