The following message accompanies all responses to requests made to FDA / CTP for tobacco product adverse event reports, data or analyses.

When reviewing or analyzing adverse event (AE) reports received by CTP, please note the following:

Individual AE reports about a particular product and the total number of AE reports for that product in CTP's AE database only reflect information **AS REPORTED** and do not represent any conclusion by FDA about whether the product actually caused the adverse events.

Reports to FDA may not include accurate or complete information, such as whether the product was used correctly, or if an individual also suffered from other medical conditions or took other tobacco products, medications, or drugs at the same time. When important information is missing from a report, it is difficult for FDA to fully evaluate whether the product caused the adverse event or simply coincided with it. The fact that an adverse event happened after a person has consumed a product does not necessarily mean that product caused the adverse event.

Because the database is constantly updated with new information, the number of reports for a given product and the content of individual reports may change over time.

AE reports received by CTP are submitted voluntarily. Generally only a small fraction of adverse events associated with any product is reported. Duplicate reports may be present, particularly if an event is reported through more than one source. In addition, use information for specific tobacco products is not well known. Therefore, accumulated reports cannot be used to calculate incidence (occurrence rates) or to estimate risk. Comparisons between products cannot be made from these data.

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 50 Years	☑ Female ☐ Male	144 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)*
03/14/2013	03/14/2013

5. Describe Event, Problem or Product Use Error

I have chemical irritation per my doctor throughout my mouth the tongue and throat and now it is going down my throat

More

6. Relevant Tests/Laboratory Data, Including Dates

I was examined by an internal medicine doctor. He told me not to use the electronic cigarette anymore I cannot smoke regular cigarettes and most foods feel like they are burning my whole mouth.

More

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

Smoker trying to quit

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Victory e cigarettes 1.8 Victory
   #2

2.	Dose or Amount	Frequency	Route
#1	2-4 puffs	About 5 times a da	
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 02/09/2013 -- 03/13/2013 (1 month 1 week)
   #2 --

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

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

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

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: ☑

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

From: Myers, Brooke
To: Rudy, Susan
Cc: Chang, Nancy
Subject: Adverse Health Event Report - Electronic Cigarettes
Date: Monday, April 01, 2013 4:43:38 PM

Hello,

I received this call today from a woman wanting to report her adverse health event regarding electronic cigarettes (E-Cigs). Her name is [redacted] and her phone number is [redacted]

[redacted] stated she purchased the BluCigs brand of electronic cigarettes and smoked one of them. After smoking the e-cigs, her lips swelled four times the size of her lip and she had trouble breathing. She then went to the emergency room and on top of the previous symptoms, she had a rash in her mouth, her face was swollen, and her throat was itchy and numb. The doctors ran test and found an antihistamine in her blood stream that came from e-cigs. She had to get steroids and an IV. She contacted the company, but couldn't get in contact with anyone because they didn't answer the call. She contacted them to inform the company of what happened, to ask for a full refund, and ask that they pay her medical bills.

The incident took place on [redacted].

Thank you,

Brooke Myers
Program Analyst
FDA/CTP/OM/M&L
9200 Corporate Blvd.
Rockville, MD 20850
Phone: 301.796.0334
Fax: 240-276-1705

Success is not the key to happiness. Happiness is the key to success. If you love what you are doing, you will be successful." ----------Albert Schweitzer

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Female from (b) (6) In confidence	(b) (6) 41 Years	☑ Female ☐ Male	180 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)*
01/01/2009	04/22/2013

5. Describe Event, Problem or Product Use Error

I visited the ER several times due to shortness of breath, heart palpatations, chest pain. Upon arrival to the ER on all occassions my blood pressure was elevated. Although all cardiac testing came back negative I did come back positive for marijuanna which was impossible. I quit E ciggs after that.

More

6. Relevant Tests/Laboratory Data, Including Dates

EKG norlam, cardiac enzymes normal, drug tes was positive with marijuana.

More

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

I have been a smaler for about 20 years with no symptoms like this prior to E ciggs or since I quit E ciggs.

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 E ciggs Regular E ciggs
   #2

2.	Dose or Amount	Frequency	Route
#1	The highest dosage, i think 32	Several times a da	Inhal
#2			

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

4. Diagnosis or Reason for Use *(Indication)*
   #1 I was a current smoker
   #2

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

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

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: E ciggs
2. Common Device Name: E ciggs
3. Manufacturer Name, City and State: I purchased in (b) (6)

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)*

E ciggs

More

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

1. Name and Address
   (b) (6)
   (b) (6) (b) (b) (6)
   Phone # (b) (6) E-mail (b) (6)

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

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

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

CTP

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

Internet Submission - Page 1/2

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

FDA USE ONLY
Triage unit
sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 60 Years	☑ Female ☐ Male	196 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
02/28/2013	04/25/2013

5. Describe Event, Problem or Product Use Error

This is in response to your request to send a report on my experience with electronic cigarettes. I've used two different brands with different ingredients except for the nicotine. Very bad experience with the first brand I used, which were the Firebrand e-cigs. I purchased these online following a recommendation. My diabetes has been in pretty good control, even if I eat something I shouldn't my sugar never went near 300 and went back to my norm around 110 or so later. I suddenly shot up, often over 400. It took a couple of weeks to realize it might be caused by the Firebrand e-cigs. These contain the polypropanol glucosamine -sp-. They

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

no allergies, Type II diabetic, peripheral neuropathy, No alcohol use in over 20 yrs. Bipolar

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☐ No ☑ Returned to Manufacturer on: 03/12/2013 *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Firebrand 24 mg, 18 mg Ludovico, Inc.
#2 blu cigs

2.	Dose or Amount	Frequency	Route
#1	as desired	every day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 1 month 02/28/2013 -- 03/18/2013
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 smoker
#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 don't hav retu	#1	don't hav ret
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Firebrand
2. Common Device Name: electronic cigarette
3. Manufacturer Name, City and State: 1023 S. Santa Fe Ave. Los Angeles, CA | 90021

4. Model #	Lot #	5. Operator of Device
on bottle liquitex	on bottle sent back	☐ Health Professional ☑ Lay User/Patient ☐ Other:
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	
Tobacco Gold,	01/01/2000	
Serial #	**Other #**	
none unless on		

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☑ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address
(b) (6)
(b) (6)
Phone # (b) (6)
E-mail (b) (6)

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

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

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

B5. Describe event or problem continued

willingly gave me a refund but they said they had never heard of it before. If you google for it, they MUST know. Then I bought the Blu e-cigs. have had no problems. They say they don't use that chemical, rather they use a vegetable based product. I am smoking the high nicotine now and plan to phase smoking out.

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	55 Years	☑ Female ☐ Male	135 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)*
03/12/2013	04/29/2013

5. Describe Event, Problem or Product Use Error

I was a cig smoker for 40 + years and have COPD. I quit smoking and was using the lowest Nicotene replacement Lozengers -2mg.- When I saw that the e cig was less nicotene than the Lozengers I started puffing them. Being a former smoker I could not help but inhale, after about a month of using the e cig I found my breathing -which had improved- was getting bad again and I was starting to cough with mucus again in the mornings. I am now back on the lozengers the cough/mucus has gone away. Would love to quit nicotine all together but "I HOPE" the lozenger will not hurt my lungs as much as inhaling.

More

6. Relevant Tests/Laboratory Data, Including Dates

None, just personal experience.

More

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

See # 5 above.

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Metro E cig .6mg Nicotek
#2

2.	Dose or Amount	Frequency	Route
#1	a few puffs	aprox 5 x day	po
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
#1 01/01/2013 -- 03/12/2013 (2 1/2 months)
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 lessen dependance on nicotene
#2

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

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

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

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

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

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

[redacted] epartment of Health and Human Services

[redacted]DWATCH

[redacted]DA Safety Information and Adverse Event Reporting Program

CTP

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

Page 1 of 3

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

FDA USE ONLY

Triage unit
sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
In confidence	59 (b) (6)	☒ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
4-11 + 4-12 2013	

5. Describe Event, Problem or Product Use Error

Electronic Ciggarettes
Sented Oil's
got my Asthma
Allergy's act up
I couldn't Breath well
& severe Congestion

6. Relevant Tests/Laboratory Data, Including Dates

[redacted]

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: Electronic Ciggarett
Strength:
Manufacturer: Different Oil Scents

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 3 Small Bottles	6 2 Hrs.	
#2 Scented Oil's Banana	2-Scents per day	

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 Friend Smoked Electric
#2 Ciggs - 2days - 6½ Hrs.

4. Diagnosis or Reason for Use *(Indication)*
#1 4-11-2013 & 4-12-2013
#2 She Smoked E-Cigg. 6½ Hrs

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 2d	#1 4-3-2013	
#2	#2	

E. 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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

Who IS Manufacturer?
I want To know

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

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

CTP

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit
sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) In confidence	(b) (6) 37 Years	☐ Female ☑ Male	163 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)*
05/29/2013	05/29/2013

5. Describe Event, Problem or Product Use Error

My husband was charging his White Rhino e-cigarette, when we heard a loud bang the product had exploded. It had shot into the hallway of our home and hit the door or our daughters room. It started a fire in our hallway. If my daughters door would not have been closed it would have landed in her bed.

CTU

MAY 30 2013

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 liquid White Rhino
   #2

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

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

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 na	#1	na
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: liquid
2. Common Device Name: White Rhino
3. Manufacturer Name, City and State: White Rhino

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address
   (b) (6)

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

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☑ Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐		☐ User Facility ☐ Distributor/Importer

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

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

UP

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

Page 1 of

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

FDA USE ONLY

Triage unit sequence #

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	(b) (6)	☒ Female ☐ Male	145 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
   - ☒ 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)*
05/02/2013	05/15/2013

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

Super Vapaur E cig exploded while charging causing 1st, 2nd and 3rd degree burns on my arm, Elbow, hip, butt & Ankle. Damage to my couch, Area rug & floor! took many pictures & have Permanent Scarring!

6. **Relevant Tests/Laboratory Data, Including Dates**

Doctors Appt on 5-15-13
Antibotics & Burn Cream

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 Super Vapour E Cig
   #2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
   #1 4-21-13 / 5-2-13
   #2

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

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

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

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

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**
2. **Common Device Name** CTU
3. **Manufacturer Name, City and State** MAY 29 2013

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

6. **If Implanted, Give Date** *(mm/dd/yyyy)*
7. **If Explanted, Give Date** *(mm/dd/yyyy)*
8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?** ☐ Yes ☒ No
9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. **Name and Address** (b) (6)
   (b) (6)

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

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

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

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

U.S. Department of Health and Human Services

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

CTP

Internet Submission - Page 1 of 3

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

FDA USE ONLY
Triage unit
sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 38 Years	☑ Female ☐ Male	310 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: 01/01/2013 *(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)*
05/28/2013	06/12/2013

5. Describe Event, Problem or Product Use Error

****No death, no hospitalization, no disability, no birth defect. This form is making me check EVERYTHING above, it has for last 17 minutes, "please check to continue" it says, frustrating! Nicomate electronic cigarette, Nicomate.com. They're all dangerous to lungs! I am trying to quit smoking and thought I would try the electronic cigarette Nicomate. I used the regular tobacco tips. It is rechargeable. I used it for 3 days, and the 3rd day went to sleep, woke up dreaming about a horrible smell in my lungs, after I woke up the smell lasted for 8 hours and was very real. It was in my lungs and was all I could breathe.

More

6. Relevant Tests/Laboratory Data, Including Dates

n/a

More

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

I smoke 3 packs cigarettes a day. 16 years now. I have asthma, allergies, sleep apnea. 2 inhalers, 2 daily allergy meds., & cpap. My lungs are

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Nicomate premium electronic ciga — Nicomate
#2

2.	Dose or Amount	Frequency	Route
#1	2 or 3 tips daily	most of day	Inhal
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 05/26/2013 -- 05/28/2013
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Stop smoking aid
#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 n/a
#2

7. Expiration Date
#1
#2

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

9. NDC # or Unique ID
none

E. SUSPECT MEDICAL DEVICE

1. Brand Name
NICOmate premium electronic cigarettes

2. Common Device Name
NICOmate

3. Manufacturer Name, City and State
NICOmate.com, 746 Spring Hill Farm Dr. Manchester, MO 63021

4. Model #	Lot # none	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☑ Other: Myself/patie
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)*

just the product and regular tobacco tips

More

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

1. Name and Address
(b) (6)

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

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

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

B5. Describe event or problem continued

Plastic/metal/chemical. Imagine the whole mixture very powerful, and it's in your lungs. Nothing would get rid of it, it's all I could inhale or exhale. I was scared and ready to have the ER check it out, but what could they do, as it did pass after 8 hours and I have not or will not touch it again. People need to know how terrible these are on your lungs! Plastic/metal/chemical in lungs was awful!

B7. Other relevant history, including preexisting medical conditions continued

sensitive to everything. Was told couldn't work in plastic factories, fibers get stuck in my lungs even with face mask on. Passed out at (b) (6) lead smelter first 2 days in a row while wearing helmet, boots, and breathing apparatus , full suit. Nurse there said I could not work around the lead. I smelled a gas leak in the inside wall of my gas station to one of the lines outside that not even the techs could find. I have serious sensitive lungs. History of a few pneumonia, bronchitis with asthma episodes. No pregnancies. White female. Alcohol, age 19 - 25. Only fatty liver, no kidney problems. Hibernoma in left foot removed (b) (6)

U.S. Department of Health and Human Services

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The FDA Safety Information and Adverse Event Reporting Program

CTP

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Self In confidence	(b) (6) 24 Years	☐ Female ☑ Male	270 lb or _____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/01/2010	06/19/2013

5. Describe Event, Problem or Product Use Error

While using a "A Clean Cigarette" brand e-cigarette, over sever months, I developed high levels of anxiety, as well as heart palpitations, both of these problems immediately stopped after I stopped use of the product.

More

6. Relevant Tests/Laboratory Data, Including Dates

EKG - August 2010 MRI - August 2010
Several blood tests - August 2010

More

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

Native American, 1 pack a day smoker, rarely drink alcohol, allergy to common binding agent common is soap. Allergy to pollen.

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Nicotine Cartridge 14mg A Clean Cigarette
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
#1 04/01/2010 -- 08/01/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Help to Stop Smoking
#2

6. Lot #	7. Expiration Date
#1 not specified	#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
none

E. SUSPECT MEDICAL DEVICE

1. Brand Name
A Clean Cigarette

2. Common Device Name
e-cigarette

3. Manufacturer Name, City and State
Saginaw, MI

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address
(b) (6)

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

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

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

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

CTP

U.S. Department of Health and Human Services

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

Internet Submission - Page 1/3

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

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event, or Date of Birth: (b) (6) 30 Years
3. Sex: ☐ Female ☑ Male
4. Weight: 179 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☑ Death: (b) (6) *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: (b) (6)
4. Date of this Report *(mm/dd/yyyy)*: 05/10/2013

5. Describe Event, Problem or Product Use Error

My son began smoking e cigarettes to quit smoking because they said they are safe. He began with the ones that look like cigarettes then moved to the type where you go online or in the store and buy all the pieces and the "liquid" called vapor cigarettes. He began the the e cigarettes and then vapor ones beginning about one year ago. He was a healthy young man who (b) (6) (b) (6) and was a healthy eater, i.e.; fruit and protein shakes, salmon and vegetables, etc, About two weeks prior to his death he began feeling like he was getting the flu. Then it turned into coughing and was taking cough medications. I

More

6. Relevant Tests/Laboratory Data, Including Dates

I am still waiting on the autopsy report. I don't know where to take the oils I have to be tested.

More

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

No allergies, White. Male. Stopped smoking tobacco cigarettes over two years ago, then cigars then e cigarettes, Stopped drinking over one and one

More

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 60% VG 40%PG 16mg OIL Vixen Vapors
#1 nicotine
#2

2.	Dose or Amount	Frequency	Route
#1		hourly	Inhal
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 06/01/2012 -- 04/02/2013
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 smoking ceasation
#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. Expiration Date
#1
#2

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Vixen Vapors
2. Common Device Name: e cigarette ViVi Nova
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

CTU

MAY 13 2013

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address
(b) (6)

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

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

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

B5. Describe event or problem continued

begged him to stop smoking those things and let me take him to the doctor. He said "they are just water and flavor and won't harm me." I read up on them and found some are made with oils and antifreeze. I pulled down the kit my son had and opened the two bottles of "liquid" that he inhaled on a consistent basis. I put a small amount on my fingers and it felt just like mineral oil. My son was inhaling antifreeze and mineral oil and was told it was safer than cigarettes. He fell asleep next to me on the couch that night, and I, just thinking he was very tired, covered him up and took the cigarette out of his hand and went to bed, I woke up at 7:40 a.m. to let our dogs out as I did every morning and he was still on the couch. I thought nothing of it at first and was telling him he needed to wake up and go get in bed, When I walked back over to the couch where he was reclined, I noticed something dark brown, like blood or something coming out of his mouth. I FREAKED OUT!!!! I am convinced it was this oil he was heating up in these e cigarettes and inhaling that took my son's life and forever changed mine. He had a doctor's appointment that day at 11:00 to see about his cough. He never made it. I will never be the same.

B7. Other relevant history, including preexisting medical conditions continued

half years ago. No medical issues known. He has pain in his wrists from massaging, but that is all I know about. I was with him every day and night. Someone needs to put a stop to this industry.

CDRH DQRS

U.S. Department of Health and Human Services

CDER

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The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # US-FDA-200018

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	40 Yea	☑ Female ☐ Male	155 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)*
01/19/2012	01/22/2012

5. Describe Event, Problem or Product Use Error

E-Cigarettes. Shortness of breath and extreme bloating.

6. Relevant Tests/Laboratory Data, Including Dates

NA

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

obviously a smoker, but I do not have this reaction to regular cigarettes.

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 E-liquid 32mg KOV

#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(if unknown, give duration)* from/to *(or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 01/09/2012 -- 01/19/2012 (9 days)	#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 smoking cessation	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 NA	#1	NA
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Knockout Vapor
2. Common Device Name: E-cigarettes
3. Manufacturer Name, City and State: Rio Rancho, New Mexico

4. Model #	Lot # NA	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)

(b) (6)

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

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

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

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

ServiceCenter Operator: BMYERS

The ERIC has referred Incident Record IM1910607 [Severity 4/ Priority 4] to the Assignment Group: CTP-OFFICE OF SCIENCE.

Assigned on: 01/07/2013 12:08:30
Customer: CTP

Phone: (b) (6)

The customer has reported the following issue:

(b) (6) called to complain about the E-Cigarette company Totally Wicked. Her 54 year old brother died suddenly in (b) (6) and before he died he told her mom that he thinks it was because of the e-cigarette. He started using e-cigs two years ago and he was a smoker previously. E-cigs was recommended by his doctor. He was diagnosed with cardio menopause. Once he started using them he started becoming short of breath.

(b) (6) just wanted to inform us so that we can look into it for other users.

She can be reached at (b) (6) or by email at (b) (6).

Please log into ServiceCenter or visit non-responsive to view, update, and resolve this incident record.

Best Regards,
The Employee Resource and Information Center

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

CTP

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

Internet Submission - Page 1

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

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Wife of e-cig smoker In confidence	56 Years	☑ Female ☐ Male	130 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)*
12/01/2012	01/07/2013

5. Describe Event, Problem or Product Use Error

My husband uses e-cigarettes. I developed an extreme allergy to the smell of the e-cigarette. When I smell the vapor -it is NOT odor free- I immediately get a headache and my sinuses begin to ache. Within 1/2 hour my voice go hoarse. Within a day my sinuses became infected. Please help get these bad products off of the market!!! I can't get my husband to quit using these hazardous products, he will only quit when they are banned.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

There was no death or hospitalization for this input, but I could not submit this form unless I checked that box.

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 all types of e-cigarettes — n/a — various
#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	9. NDC # or Unique ID
#1 n/a	#1	n/a
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: various
2. Common Device Name: e-cigarette
3. Manufacturer Name, City and State: various

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address

Phone # | E-mail

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

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

U.S. Department of Health and Human Services

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Internet Submission - Page 1 / 2

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
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FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
[redacted] In confidence	26 Years	☑ Female ☐ Male	____ lb or 51.5 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)*
01/12/2013	01/13/2013

5. Describe Event, Problem or Product Use Error

12 hours after inhalated a 6mg vanilla dose of electronic cigarretes, the patient had a rash on her left and right arm. The left arm rash covered from the wrist to the elbow, while the right arm covered just the wrist. Also she was not able to talk well, her throat was closed. The patient did not relate the rash to the electronic cigarrete substance, so the next day, she smoked again, but the rash extended to her abdomen, the back, and the cheeks. Also the throat was completely closed, and she was not able to talk. After 12 hours without smoking, the throat began to open again. No medications were administered during the reaction, or

More

6. Relevant Tests/Laboratory Data, Including Dates

None

More

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

Smoking: Camel Previous e-cigarrete brand JLS 11mg, blueberry -no reactions occured- during 1 week prior to the rash.

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 e-liquid JLS Vanilla Dekang
   #2

2.	Dose or Amount	Frequency	Route
#1	6mg/30ml		Inhal
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
   #1 01/10/2013 – 01/13/2013
   #2 – –

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

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

6. 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 No Lot	#1	NA
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: ELECTRONIC CIGARRETE
2. Common Device Name: JLS e-cigarrete
3. Manufacturer Name, City and State: Comercializadora JLS México Salamanca 73, Col. Roma, Mexico Distrito Federal, Mexico, CP. 06700

4. Model #	Lot #	5. Operator of Device
vapErs-GoU 650 mAh	NA	☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☑ Lay User/Patient
Serial #	Other #	☐ 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)*

NA

More

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

1. Name and Address
   [redacted]

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Other Health	☐ Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑		☐ User Facility ☐ Distributor/Importer

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

B5. Describe event or problem continued

before the reaction.

U.S. Department of Health and Human Services

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Internet Submission - Page 1

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See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
spouce In confidence		☐ Female ☑ Male	245 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)*
	01/21/2013

5. Describe Event, Problem or Product Use Error

When I have been around people smoking the Electronic Cigarettes I have ended up with pnuemia and a second time I had brontis. When I am around regular cigarettes this has also happened.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

White seldom use alcohol

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Electronic Cigarettes ? ?
   #2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration)* from/to *(or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 --	#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	?
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Electronic Cigarettes
2. Common Device Name: Electronic Cigarettes
3. Manufacturer Name, City and State: ?

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

I did not use this product but a friend did and I was sick for about two weeks each time.

More

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

1. Name and Address

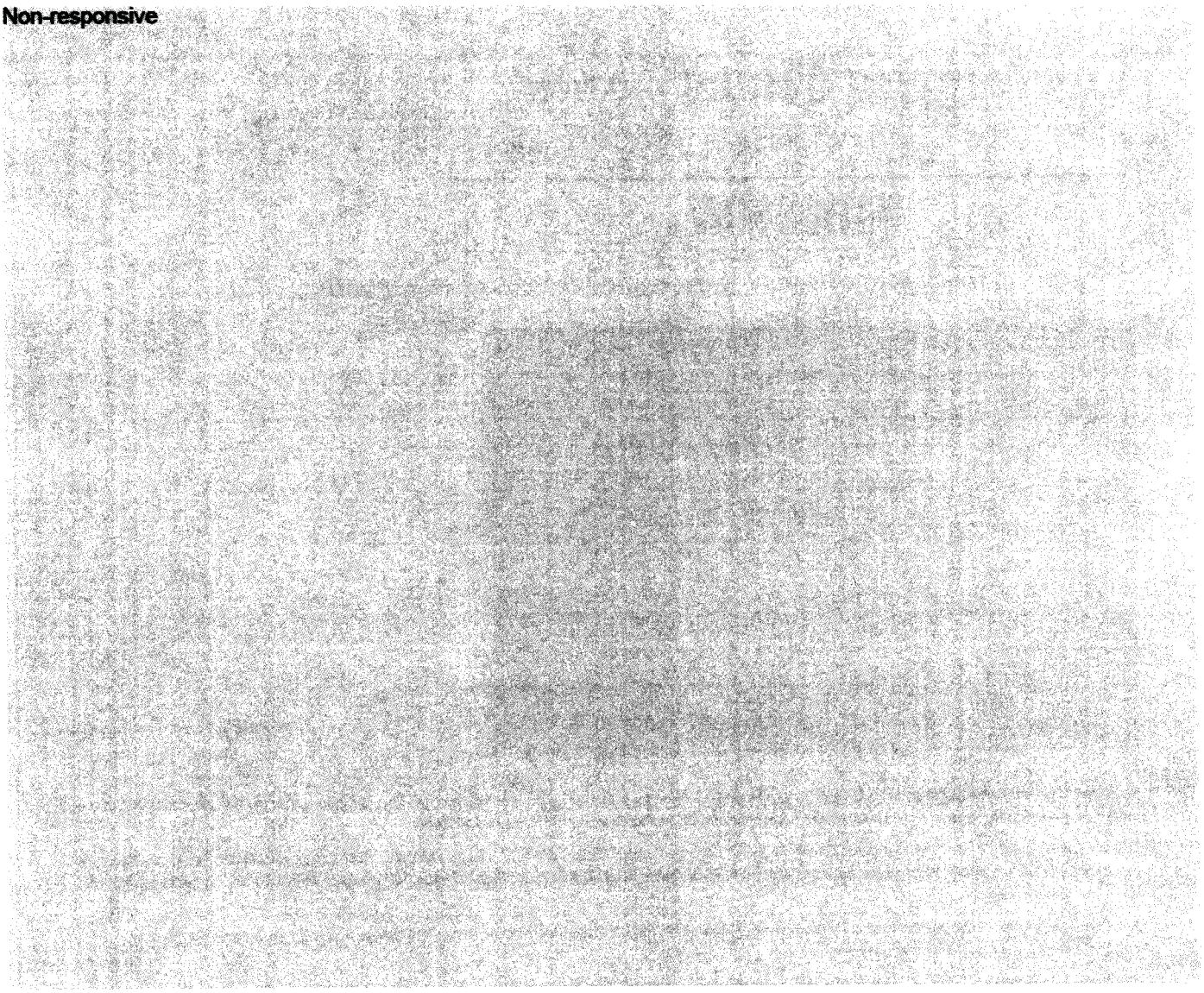
Phone #	E-mail

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

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

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

Non-responsive



From: (b) (6)
Sent: Sunday, January 22, 2012 4:41 PM
To: AskCTP
Subject:

can you check into electronic ciggaretts causing
pleurisy

i magicly have it after starting electronic ciggaretts

Los Angeles Times | NATION

NATION NOW

Are smokeless cigarettes safer? E-cig explodes in smoker's mouth

February 16, 2012 | 9:54 am

Electronic cigarettes and cigars are billed as a safer way to get a nicotine high, but a Florida man learned just how dangerous they can be this week. One of the devices exploded in his mouth, ripping out part of his tongue and several teeth while badly burning his face.

"He is very, very lucky," Fire Chief Joseph Miller of the North Bay Fire Control District told The Times. The man, identified as Tom Holloway, 57, was taken to a local hospital for treatment Wednesday, then transported to an Alabama hospital that specializes in burns. He has since been released. "It could have been a lot worse," Miller added.

Emergency responders said the device that Holloway was holding in his mouth acted like "a bottle rocket." Holloway was in his home office at the time, and some carpet and chair cushions also burned.

Electronic cigarettes and cigars -- commonly called e-cigarettes and e-cigars -- are all the rage even though their safety is hotly debated. They use a nicotine cartridge and a battery. The battery creates an electrical charge that releases the nicotine vapor. The user inhales that familiar shot of nicotine, without the smoke.

Until now, controversy has largely centered on federal regulatory issues and whether consumers are being misled by a device that some say could actually be more toxic than regular cigarettes because of the secondary chemicals used. But this week's explosion will obviously raise more immediate safety questions.

As you might imagine, the incident -- and ensuing publicity -- isn't good P.R. for the burgeoning industry of smokeless cigarettes and cigars.

Thomas Kiklas, co-founder of the Tobacco Vapor Electronic Cigarette Assn. told The Times that he believes the device that Holloway used was not the commonly sold kind, but a specially modified device designed to give the user a turbo-charged blast of nicotine. (He likened it to the difference between a push lawn mower and a gasoline-charged lawnmower.) He said on his site that it is too soon to jump to any conclusion about possible product failure.

Miller, the Niceville, Fla.-based fire chief, said he'd never heard of the device before, but assumes that it was a one-time fluke. "When I heard 'electronic cigarette,' I said, 'What in the heck is that?' "

The injured man has since called to thank the emergency responders for their quick action. "He was very, very thankful."

ALSO:

At Heart Attack Grill, diner's symptoms weren't fake

Josh Powell won't be buried next to sons; officers buy plots

New Jersey expected to approve gay marriage; Christie vows veto

-- Rene Lynch
Twitter / renelynch

File photo: An e-cigarette. Credit: Gerry Broome / Associated Press

(b) (6) ,

Nice to talk with you today. I have a number of pictures but am unsure how to send all in one email so I will send them separately (1 picture/ email). The resolution of these pictures are not great but the whitish areas in the changed gingiva are actually areas of denuded bone.

(b) (6)

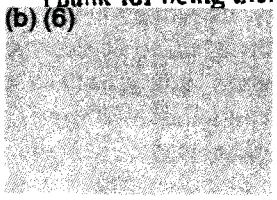
Today, I received an interesting call from a local dentist who saw the article on e-cigs and thus got my name. She told me said she has a current patient who has been a long term user of the e-cigarette who had significant pathology in his oral mucosa that she believes was caused by the e-cigarette. It makes sense that if there are side effects associated with using e-cigs that they would be found in the mouth. However, I have not previously heard of problems with destroying oral tissue in the mouth linked to e-cigarettes. However, it makes sense that dental professionals would be the first to observe adverse consequences if there are any.

I advised the dentists who called me to do two things: 1) write up a case study on her observations with this patient (she sent me pictures which are attached) so her dental colleagues might be alerted to this potential adverse consequence; and 2) submit an adverse event report to FDA.

I told her I would take care of the later so consider this note to be the adverse event report since I'm not sure if there is a formal way to do this for tobacco products under FDAs authority. The attachment which includes the e-mail I received includes the dentist's name and contact information so perhaps you can have someone speak with her directly. She seemed very credible. The patient is coming back to see her so there would be an opportunity to asses if the pathology changes with discontinuation of the e-cig. She told me the patient is a bit compulsive and has been using the e-cig continuously.

(b) (6)
Professor,
Department of Psychiatry & Behavioral Sciences
Medical University of South Carolina

3/4/12
To The FDA
To Whom it may concern
I feel I need to inform you guys, I have had a real bad experience with The E Cigarette.
About A month ago I decided to try and quit or at least cut down on tobacco, so I purchased the E-Cig
The brand was called VapCigs, VC Plus.
I used them on a moderate basis, nothing excessive, The first week, my cravings seemed to be under control.
Around the second week I noticed some changes, with my appearance, my skin on my face was like I had gotten a real bad sunburn and the skin on my legs and arms was real rough, almost scaly. And very itchy, but hurt to touch.
I did not link this to the E-cigarette at the time.
Around the 3rd week, I started getting very sharp pains across my chest and some very bad headaches, and my blood pressure was starting to get very high, but my heart rate was low for me.
Since this E-Cig was the only thing new in my life style I felt I needed to stop using the product.
This is the 4th week, My skin is getting better and the pains in my chest have gone now, I am not in the frame of health, as before I started The E-Cig, but seem to be getting there.
I really think you all need to take a look at the product, for safety reasons at least.
Thank for being there.
(b) (6)



U.S. Department of Health and Human Services

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Internet Submission - Page 1

Form Approved: OMB No. 0910-0291, Expires 10/31/08
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FDA USE ONLY

Triage unit sequence # US-FDA-205000

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	220 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)
03/10/2012	04/12/2012

5. Describe Event, Problem or Product Use Error

when taking a drag start coughing seeing dots urinating on self when coughing stop breathing gasping for air takes 15 minutes for attack to stop

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.)

fibromyalgia back pain bipolar anxiety disorder

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 NJoy
#2

2. Dose or Amount	Frequency	Route
#1 1 puff	20 puffs	
#2		

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

4. Diagnosis or Reason for Use (Indication)
#1 smoking cesation
#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. Expiration Date
#1
#2

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

elavil tramadol hydrocodone carbamzepine klonopin

G. REPORTER (See confidentiality section on back)

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

Phone # (b) (6)

E-mail (b) (6)

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

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

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

[redacted]

H6. FDA Comments

Drug	Manufacturer	Dose	Unit	Route	Frequency Dosage Interval Unit			Is Concomitant

Diagnosis for Use	Start Date	End Date	Duration	Unit

FDA Comments:

```
WILSONJ: |*********|  2012-04-13-07.47.07  |*********|
USFDAMWVOLUNTARY_205000_17216_20120412.xml
Route To: Misc.     :           : Paper
Need copy for CTP
```

DQRS

U.S. Department of Health and Human Services

MEDWATCH

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Internet Submission - Page 1

Form Approved: OMB No. 0910-0291. Expires: 10/31/08
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FDA USE ONLY

Triage unit sequence # US-FDA-206274

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
1520	20 Yea	☑ Female ☐ Male	122 lb or ____ kg
In confidence			

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/02/2012	05/05/2012

5. Describe Event, Problem or Product Use Error

The product name is lava it is the potpurri that many people are smoking my boyfriend is smoking it and it has cause some serious problems it has cause him memory loss, seizures, he can not speak or walk when he is smoking this stuff he has became very very addicted to this lava im very concered with what it is doing to him. I really woulkd like this stuff to be banned and taken off the shelves of the stores... The store that he keeps buying it from is Exxon Mobile and the adress is, (b) (6) And there phone number is (b) (6) Please i am begging you to please help me and everyone else take this stuff off

6. Relevant Tests/Laboratory Data, Including Dates

RECEIVED
MAY 07 2012
MEDWATCH CTU

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 Lava extra strengh Made in USA
#2

2. Dose or Amount	Frequency	Route
#1 3 grams		
#2		

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

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

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

6. Lot #
#1 3621171146
#2

7. Expiration Date
#1
#2

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

9. NDC # or Unique ID
3621171146

E. SUSPECT MEDICAL DEVICE

1. Brand Name
lava

2. Common Device Name
lava

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 # 3621171146	

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)
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

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

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

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

B5. Describe event or problem continued

he shelves before i lose my boyfriend.. He is not the same person i need help and everyone else that smokes this stuff i hear stories about it... It is really scaring me bad i need help for this before my Daughters Father is brain Dead or has altimerz he has became very addicted to this stuff its rediculous

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # US-FDA-206359

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
rescue911 in confidence	(b) (6)	☐ Female ☑ Male	180 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)*
	05/07/2012

5. Describe Event, Problem or Product Use Error

Every since i began using the ProSmoke electronic cigarette, my gums have started bleeding. I was wondering if you had other reorts of this happening?

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.)*

none

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 ProSmoke e-cigarette
#2

2. Dose or Amount	Frequency	Route
#1	daily	
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 03/01/2012 -- 05/07/2012	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

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

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name prosmoke
2. Common Device Name e cigarette
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)
(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: ☐

H6. FDA Comments

Drug	Manufacturer	Dose	Unit	Route	Frequency Dosage	Interval	Unit	Is Concomitant

Diagnosis for Use	Start Date	End Date	Duration	Unit

FDA Comments:

```
WALKERC: |*********|  2012-05-08-08.39.55  |*********|
USFDAMWVOLUNTARY_206359_18373_20120508.xml
Route To: Misc.     :            : Paper
Center for Tobacco Products Item
```

CTP (center for tobacco products)

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

Internet Submission - Page 1

Form Approved OMB No. 0910-0291, Expires 10/31/08
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FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) In confidence	(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)
06/29/2012	06/29/2012

5. Describe Event, Problem or Product Use Error

On 06/07/2012, patient reported coughing after using an e-cigarette or Electronic Nicotine Delievery System -ENDS- product distributed by www.acleancigarette.com. The nicotine concentration was 24mg -2.4%/mL-per cartridge. She described the coughing similar to an asthma attack. The coughing associated with puffing on the ENDS continued over the duration of 3 weeks after starting this product. The patient was notified to discontinue the product on 06/29/2012. This writer contacted the distributor on 06/29/2012 to confirmed that the product contained vegetable glycerine which has been implicated in pulmonary problems -see article by McCauley

More

6. Relevant Tests/Laboratory Data, Including Dates

None

More

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

Recent diagnosis of Lung Cancer and scheduled for surgical resection in 07/2012, Tobacco dependence -1.5ppd-, Schzoaffective disorder, hypertension,

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Electronic cigarette -ENDS- 24 mg nicotine acleancigarette.com

#2

2.	Dose or Amount	Frequency	Route
#1	1 puff	QID	Inhal
#2			

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

#1 06/07/2012 06/29/2012

#2

4. Diagnosis or Reason for Use (Indication)

#1 Smoking Cessation

#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: acleancigarette.com

2. Common Device Name: Electronic nicotine delivery system -ENDS- or

3. Manufacturer Name, City and State: acleancigarette.com

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

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

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

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

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

B5. Describe event or problem continued

L. Chest 2012;141-4-:1110-113-. The distribitor also admitted that an undisclosed number of clients had reported "allergic reactions" -no details- to the product.

B7. Other relevant history, including preexisting medical conditions continued

hyperlipidemia, Barrett's Esophagitis, GERD, Diabetes, type 2, Obesity, Chronic lower back pain.

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

CTP

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

Internet Submission - Page 1 / 2

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

FDA USE ONLY

Triage unit sequence #

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: 170 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): 05/25/2012
4. Date of this Report (mm/dd/yyyy): 07/03/2012

5. Describe Event, Problem or Product Use Error

In an attempt to stop smoking cigarettes I decided to use the electronic cigarette. I had surgery scheduled on April 9, 2012 for placement of two stents as part of preventative care associated with a heart condition. Knowing how serious my condition is, I decided to start my cigarette cessation one week before the surgery. On or about March 31st, I purchased a Premium Brand e-cigarette system from As Seen on TV (b) (6) starting out with 16 mg menthol flavor. Almost immediately, because I could smoke e-cigarettes in places where I cannot smoke regular cigarettes and believing that they were not harmful

More

6. Relevant Tests/Laboratory Data, Including Dates

See section 5

More

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

See section 5

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Premium Electronic .06 - .16 Premium Cigarette
#2

2.	Dose or Amount	Frequency	Route
#1	.06 - .16	4-5 Cart.-daily	Inhal
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 03/31/2012 -- 05/29/2012
#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 To Stop smoking
#2

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

6. Lot #
#1 No Lot #s post
#2

7. Expiration Date
#1
#2

9. NDC # or Unique ID
none

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Premium
2. Common Device Name: Electroic Cigarette and Cartridges
3. Manufacturer Name, City and State: Premium - No location info on product telephone number listed as 866-242-9210

4. Model #	Lot #	5. Operator of Device
	None listed	☐ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Lay User/Patient
Serial #	Other #	☐ Other

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # (b) (6)
(b) (6)

2. Health Professional? ☐ Yes ☑ No
3. Occupation: Consumer/Non-Health
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: ☐

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

B5. Describe event or problem continued

to my health -based on advertisements-, I constantly smoked - about 4-5 cartridges per day. As planned on 4/9/12, I had the surgery; however additional stents were not placed because my surgeon determined that the affected arteries were not significantly blocked. I continued with smoking the e-cigarette including the night of the surgery. Immediately after the medical procedure I experienced a severe rash on my inner thigh of both legs and severe joint paint. Due to the timing of the surgery, I attributed these new symptoms to after-affects. Over the next couple of months, I continued to smoke the e-cigarette decreasing my intake from 16 mg, to 11 mg, and finally to 6mg while continuing the amount of cartridges of 4-5 per day. -I typically purchased these cartridges directly from www.premiumecigarette.com/.- During this time, my joint pain increased to the point of debilitation. The pain was excruciating and I could barely walk. It was so bad each day I that I thought it could not get any worse, yet somehow it did. My family doctor referred me to an orthopedic doctor and prescribed me ibuprofen - which provided some relief, but not nearly enough. Tests were ordered. -Thankfully, my test results for arthritis and cancer were negative.- At about this time, I found information over the internet to suggest that other people using the e-cigarette had experienced similar symptoms of joint pain. I immediately stopped smoking the e-cigarette and started to feel somewhat better. Basically, the escalating aspect ceased - in other words, it never got any worse. However, still the pain has been lingering. Even before reading the 2009 FDA press release -just read that today in search of somewhere to report this information-, I figured I was suffering the effects of chemical poisoning. The orthopedic specialist advised if my pain was based on toxicity, it would take approximately 3 months for expulsion. When I called my family doctor to determine if there is a way to hasten removal of the toxins in my system, he recommended purchasing a liver detoxification kit which I started last week. Hopefully, it will work. Just this past weekend I developed a rash on my arms similar to the one that had been on my inner thighs - do I dare hope that this is a sign that the toxins are departing? If there is an antidote to the type of poisoning that the e-cigarettes inflict on the body that the FDA is aware of, I welcome that you contact me with the information so it can be passed onto my medical personnel.

CTP

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit
sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence		☐ 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)
06/17/2012	07/07/2012

5. Describe Event, Problem or Product Use Error

After using an e-cigarette from the brand V2 Cigs, an recent incident sent me to the emergency room. While I have been using e-cigarettes for a while, it is the first time something like this happened. I recently decided to try the V2 Cigs because of their popularity. However, upon starting to use the product, I notice that the nicotine cartridges appeared to be overheating. I switched with other cartridges of from the same V2 brand but each time, they overheated very quickly after just a few puffs. After a couple of days of using the brand, I started feeling unwell, nauseated and rashes appeared on my chest. Finally, on June 17th, I

More

6. Relevant Tests/Laboratory Data, Including Dates

Finally, on June 17th, I started vomiting violently for several hours and I decided to go to the emergency room because I felt so unwell I started getting concerned. While the doctors did not initially find anything life-threatening at the time, everything seemed to indicate either food poisoning

More

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

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 V2 Cigs Electronic Cigarette Medium V2 Cigs

#2

2. Dose or Amount	Frequency	Route
#1		Buccal
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 06/10/2012 -- 06/17/2012	#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	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: V2 Cigs
2. Common Device Name: Electronic Cigarette
3. Manufacturer Name, City and State: V2 Cigs

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

V2 Cigs, Nicotine replacement

More

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

Phone #	E-mail

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

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

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

B5. Describe event or problem continued

started vomiting violently for several hours and I decided to go to the emergency room because I felt so unwell I started getting concerned. While the doctors did not initially find anything life-threatening at the time, everything seemed to indicate either food poisoning or an allergy. It wasn't until they received the results of the blood work that they were able to make a final diagnosis. They concluded, based on the test results that I my body was reacting to the absorption of a rather significant quantity of nicotine. It was assume that the cartridges were probably leaking some of their liquid substance which I appeared to have ingested unknowingly. More puzzling, doctors also discovered traces of diethylene glycol in my blood. While they asked me if I had been in contact with any household chemicals or other products, they could not exactly conclude as to how I had been contaminated by that substance. They explained that I was likely the reason for my vomiting and that additional test were needed to see if any organs such as my liver or kidneys had been damaged. However, doctors believe that everything seems to point towards the use of the electronic cigarette. I have decided to sue the company based on the advice of the doctors who believe the product may be a health risk to others. While I am still waiting on the results of other tests conducted after the incident, the cost of my medical bills has escalated and the use of the product may have seriously compromised my health. I am providing you with this information in the hope that you conduct an investigation on your end so other customers do not find themselves in the same situation as me.

B6. Relevant tests/laboratory data, including dates continued

or an allergy. It wasn't until they received the results of the blood work that they were able to make a final diagnosis. They concluded, based on the test results that I my body was reacting to the absorption of a rather significant quantity of nicotine. It was assume that the cartridges were probably leaking some of their liquid substance which I appeared to have ingested unknowingly. More puzzling, doctors also discovered traces of diethylene glycol in my blood. While they asked me if I had been in contact with any household chemicals or other products, they could not exactly conclude as to how I had been contaminated by that substance. They explained that It was likely the reason for my vomiting and that additional test were needed to see if any organs such as my liver or kidneys had been damaged. However, doctors believe that everything seems to point towards the use of the electronic cigarette.

U.S. Department of Health and Human Services

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MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1 of 2

FDA USE ONLY
Triage unit
sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	185 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)*
07/13/2012	07/13/2012

5. Describe Event, Problem or Product Use Error

i was using "premium" electronic cigarettes ,and began finding when i couged up phlem it contained blood , these were 16mg nicotine,this had happend before but i did not associate it with e-cigarette use but i found when i stopped using them the blood disappeared from my phlem i think there is a direct correlation between users ,,furter i feel fda should investigate and advise the public if these e-cigs are safe or not

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

i am copd diagnosed and was trying to stop smoking by using e-cigs but it appears they were more invasive since in 49yrs of smoking did i cough up

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 premium electronic cigarette 16mg nicotene premium E cigarette
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 01/11/2012 07/10/2012	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply
4. Diagnosis or Reason for Use *(Indication)* #1 aid to stop tradictional smoking	8. Event Reappeared After Reintroduction?
#2	#1 ☐ Yes ☐ No ☐ Doesn't Apply
6. Lot # #1 #2	7. Expiration Date #1 #2
	#2 ☐ Yes ☐ No ☐ Doesn't Apply
	9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: premium
2. Common Device Name: e-cigarette
3. Manufacturer Name, City and State: made in china

4. Model #	Lot #	5. Operator of Device
tobaco 16mg		☐ 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)*

More

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

1. Name and Address
(b) (6)

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

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐		☐ User Facility ☐ Distributor/Importer

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

B7. Other relevant history, including preexisting medical conditions continued

blood i would note i am not currently smoking

MedWatch 3500A

The FDA Adverse Event Reporting Program

6968T72-4-00-01

KY reporting of duct problems and product use errors

(Internet) Submission - Page 1

DQRS

Triage unit sequence # 424631

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	160 lb or ____ kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

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)
07/19/2010	07/20/2010

5. Describe Event, Problem or Product Use Error

After using a e-cig, felt very sick and dizzy then started sweating badly. felt the need to go to sleep early and while in bed started to vomit.

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JUL 21 2010
MEDWATCH CTU

More

6. Relevant Tests/Laboratory Data, Including Dates

DSS
JUL 21 2010

More

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

smoking

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (if known, product code)

	Name, Strength, Manufacturer	Lot #	Exp. Date
#1	E-Cigarette	Itsty	Health E-Cigarette
#2			

	2. Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use (if unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 07/15/2010 -- 07/19/2010	#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 Smoker	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 none	#1	none
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

23

More

G. REPORTER (Voluntary Reporting Only)

1. Name and Address

me
here
there VA 23061

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: ☑

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

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MedWatch

The FDA Safety Information and Adverse Event Reporting Program

Individual Safety Report

...Y reporting of ...ct problems and ...ETUOS

- Page 1 /

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

FDA USE ONLY
Triage unit
Log/Incoming # 348160

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6)	23 Years	☐ Female ☑ Male	160 lb or ___ kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

Check all that apply:

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

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
08/20/2008	08/28/2008

5. Describe Event, Problem or Product Use Error

Electronic cigarette was purchased from E-cig.com as a supposed safe alternative to cigarettes. E-cig contains propylene glycol, deemed GRAS -generally recognized as safe-. Shortly after inhalation of vaporized 'E-liquid', symptoms similar to ethylene glycol poisoning were experienced -confusion, stupor, slurred speech, intense kidney/ liver pain, inability to form coherent thoughts, depression, anger, nausea-. Symptoms persisted for at least 24 hours, followed by long, painful headache. This experiance was repeated several times, with 'E-liquid' containing less nicotine to rule out nicotine overdose. Even a tiny amount of this product.

More

6. Relevant Tests/Laboratory Data, Including Dates

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SEP 0 2 2008
MEDWATCH CTU

More

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

smoking prior to experience

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (if known, give NDC #)

#1 E-cig Tmg nicotine E-cig
#2

2. Dose or Amount	Frequency	Route
#1 several inhalations		Inhal
#2		

3. Dates of Use (if unknown, give duration)	5. Event Abated After Use Stopped or Dose Reduced?
#1 08/16/2008 -- 08/27/2008	#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 cigarette replacement	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Cixi E-CIG Technology Inc. Ltd.
2. Common Device Name: E-cig, E-cartridge, E-liquid
3. Manufacturer Name, City and State: Cixi E-CIG Technology Inc. Ltd. No. 145 Dangshan N. Rd. 2nd Fl. High-Tech Building Cixi Zhejiang 315300 China

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

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

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

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

DSS
SEP - 2 2008

E. CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

25

More

F. REPORTER (Person Submitting Report)

1. Name and Address
(b) (6)

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: ☑

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

348160

Individual Safety Report

[redacted]

MEDWATCH

FDA of adverse events and product problems

Internet Submission - Page 2

B5 Describe event or problem (continued)

when inhaled, induces these symptoms. Propylene glycol is NOT SAFE, and should not be allowed for human consumption, ESPECIALLY not for inhalation use. Please investigate propylene glycol and do something about these companies selling this dangerous product to Americans.

DSS

SEP - 2 2008

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

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

Individual Safety Report
6094822-1-09-01

KH / CDER

UNTARY reporting of
ns, product problems and
product use errors

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

The FDA Safety Information and Adverse Event Reporting Program

Intranet Submission - Page 1 DQRS

Triage Unit sequence # 429756

PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	58 Years	☐ Female ☑ Male	228 lb or ____ kg

ADVERSE EVENT OR PRODUCT PROBLEM

Check all that apply:

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

2. Outcome 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)
04/03/2010	09/15/2010

5. Describe Event, Problem or Product Use Error

I am writing with a concern about MJoy electronic Cigarettes. I purchased Mjoy in late February 2010 in a effort to reduce smoking. In mid March I started feeling ill. This lead to a emergency visit to a local hospital with just minutes to spare before I would have possibly died according to hospital staff. I had suddenly contracted a severe case of Pneumonia with my lungs filled with water and a heart rate, which could not be controlled. It took the hospital several days to get my heart rate under control. Now this caused congestive heart failure. After a week in the hospital I was sent home with new medications which I now must

More

6. Relevant Tests/Laboratory Data, Including Dates

DSS RECEIVED
SEP 16 2010 SEP 16 2010
MEDWATCH CTU

More

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

More

CONCOMITANT MEDICAL PRODUCTS

Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

SUSPECT MEDICAL PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 MJOY Electronic Cigarettes MJOY
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use (if unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?	8. Event Reappeared After Reintroduction?
#1 03/01/2010 -- 04/03/2010	#1 ☑ Yes ☐ No ☐ Doesn't Apply	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)
#1 normal as advertised
#2

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

SUSPECT MEDICAL DEVICE

1. Brand Name: MJOY
2. Common Device Name: Electronic Cigarettes
3. Manufacturer Name, City and State: unk

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

ADMINISTRATIVE AND FOLLOW-UP INFORMATION

Product names and therapy dates (exclude treatment of event)
(b) Hospital - (b) (6) 4 days

More

REPORTER INFORMATION

1. Name and Address
(b) (6)

Phone # (b) (6) Email (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, please check "1" in this box: ☐

FORM FDA 3500 (9/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

69 = 40

Individual Safety Report

004122-1-00-02

429756

MEDWATCH

FOR VOLUNTARY reporting by health professionals of adverse events and product problems

Internet Submission - Page 2

H3. Describe event or problem (continued)

take to control my heart rate, which was never an issue before. And I have never been sick or ill and felt just fine; until suddenly taken ill after use of Njoy. The medical staff said that inhaling water vapors is what rapidly caused my lungs to fill with fluids and thus threw me into Pneumonia and then congestive heart failure. Since that time I have not been the same person. I am always short of breath. I would be willing to speak with a FDA representative regarding this issue. I know that the FDA is attempting to regulate the industry and it should.; had I knew the dangers I would have never purchased the product. Sincerely,

(b) (6)

DSS

SEP 16 2010

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

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

U.S. **Individual Safety Report**

Th 8752488-2-00-01
Adverse Event Reporting Program

RY reporting of
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se errors

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

FDA USE ONLY
Triage unit sequence # 4 420009

DQRS
CDRH

A PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
In confidence	22	☐ Female ☑ Male	160 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)
5/25/2010	5/30/2010

5. Describe Event, Problem or Product Use Error

Several days after receiving and beginning to use the Blu Cigs e-cigarette, I developed a persistent cough in addition to aches and sinus congestion (5/25). By the morning of 5/29 my condition became much more severe, with symptoms including difficulty breathing/ shortness of breath, chest pain, severe cough, joint pain, sinus congestion, sore throat and laryngitis. Upon seeing a doctor, I was diagnosed with pneumonia. The doctor prescribed me Levaquin and today (5/30) my condition is significantly though not completely improved.

6. Relevant Tests/Laboratory Data, Including Dates

Chest X-ray (5/29/2010), Positive for Pneumonia

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatitis, pregnancy)

Light smoker (< 1 pack a week)

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JUN 01 2010
MEDWATCH OTLL

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JUN 01 2010

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: Starter Kit
Strength: Light
Manufacturer: Blu Cigs

#2 Name:
Strength:
Manufacturer:

	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 5/23-5/26
#2

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

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

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

6. Lot #	7. Expiration Date	8. NDC # or Unique ID
#1	#1	
#2	#2	

E SUSPECT MEDICAL DEVICE

1. Brand Name: Blu Cigs
2. Common Device Name: E-Cigarette
3. Manufacturer Name, City and State: Blu Cigs, Unknown (www.blucigs.com)

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

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-Use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☑ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G REPORTER (Should be kept confidential)

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

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

2. Health Professional? ☐ Yes ☑ No
3. Occupation: Non-Healthcare Profession
4. Also Reported to: ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer
6. If you do NOT want your identity disclosed to the manufacturer, please put an "X" in this box: ☑

PLEASE TYPE OR USE BLACK INK

(1)

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.

OMB No. 0910-0291

Individual Safety Report

6735304-7-00-01

ARY reporting of roduct problems and t use errors DQRS

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

Triage Unit sequence # 418943

Adverse Event Reporting Program

- Page 1

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6)	(b) (6)	☐ Female ☑ Male	210 lb or ____ kg

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem (e.g., defective/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)
05/18/2010	05/19/2010

5. Describe Event, Problem or Product Use Error

electronic cigarette purchased from esmoke.net was advertised as "not having ANY carcinogens" and "all cartridges from raw US materials" I visited the head location and saw materials being shipped in from China for use in the product and the e-cigarette had chemical taste to it and malfuunctioned. This can be a serious health threat to the people seeking benefits from this product. FDA needs to investigate ASAP

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MAY 20 2010
MEDWATCH CTU

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

DSS
MAY 20 2010

More

Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

1. Name, Strength, Manufacturer (from product label)
#1 e-cigarette www.esmoke.net
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (if unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 --	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 --	#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	9. NDC # or Unique ID
#1	#1	
#2	#2	

OTC

1. Brand Name www.e-smoke.net
2. Common Device Name electronic cigarette
3. Manufacturer Name, City and State esmoke.net in Lakewood NJ

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

Product Names and therapy dates (exclude treatment of event)
#2

More

1. Name and Address
(b) (6)

(b) (6)

(b) (6)

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

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

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

51 Compliance

CDRH

Individual Safety Report

Adverse Event Reporting Program

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1 CDER

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

FOR FDA USE ONLY
Triage unit sequence # 414776

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 50 Years	☑ Female ☐ Male	130 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)
03/17/2010	04/09/2010

5. Describe Event, Problem or Product Use Error

I bought a a item from Innovative Smoking to stop smoking and paid 220.33 for the item it was a kit. I was told that it was fda approved. I got very ill withing a half hour of returning home. I went back to the cart were I boutht and the manager try to refund my money. But his computer would not let him. He agreed that because I became ill I would want to return the unused product. I was told that I would have to send a email to the home company,which I did. I have never heard from them. I have been disabled for ten years I have a form of cancer and thought that this would maybe help me quit smoking. I am on a fixed income and can ill aford

More

6. Relevant Tests/Laboratory Data, Including Dates

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APR 13 2010 APR 13 2010
MEDWATCH CTU

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

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Innovative Smoking High sophistication needs innocetive

#2

2. Dose or Amount	Frequency	Route
#1 high--low 0		po
#2		

3. Dates of Use (if unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 03/17/2010 -- 03/17/2010	#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 to stop smoking	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Innovative Smoking
2. Common Device Name: E cigarette - E Light-
3. Manufacturer Name, City and State: E Light

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

6170 Grand Av. Gurnee, Il. 60031 - this address is were I bought It no other address given.-

F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

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

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

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

414776

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

B5. Describe event or problem continued

to but a product that makes me ill. I do not know if I had a interaction with the meds that I take . The manager told me that I should not and that the product was safe and approved by the fda. There website also states that this product is approved by the fda. I would not of bought it if I had known that it wasn't. Thank You for your time.

DSS
APR 13 2010

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

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

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CDER

Y reporting of
ict problems and
product use errors

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

The FDA Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1 DQRS

FDA USE ONLY
Triage unit sequence # 410252

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) In confidence	28 Years	☐ Female ☑ Male	200 lb or ___ kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

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)
03/01/2010	03/03/2010

5. Describe Event, Problem or Product Use Error

After 3 days of using Blu brand electronic cigarettes i experienced what i may only guess to be my first migrane in my life. above my left eye a pounding pain and an extreme sensitivity to light and sound. effects went away when i stopped smoking the ecigarrete but came right back when i tried to smoke it again later. since stopping the product i have experienced none of these effects. why is something not even tested allowed to be sold in the usa?

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Blu E-Cigarrete Full Flavor Blu
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (if unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 --	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	9. Event Reappeared After Reintroduction?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	8. NDC # or Unique ID
#1 unknown	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

OTC

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

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

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

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

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

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MAR 0 4 2010
MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

DSS
MAR – 4 2010

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

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: ☐

U.S. Department of Health and Human Services

Individual Safety Report

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

Y reporting of
uct problems and
errors
- Page 1

Triage unit sequence # 388266

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 45 Years	☐ Female ☑ Male	145 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 Defects
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
08/07/2009	08/07/2009

5. Describe Event, Problem or Product Use Error

Yes, I bought an electronic cigarette and want to report a very bad adverse effect. Your ban of them. As a two pack a day smoker for 25 years, I thought there was no hope. I tried all the NTRs that the market had to offer, even non conventional ones -hypnosis, voodo doctor blck magic, etc-, yet I could not pull myself away from the deadly cigarettes. I then tried electronic cigarettes months ago. My quality of life has dramatically increased since I started using them. So far - I can breath again - I have more energy - I no longer have chest pains waking in the morning - I no longer cough up a lung - My primary physician, who

More

6. Relevant Tests/Laboratory Data, Including Dates

Look up your own test results of the electronic cigarette and compare it to a real one.

More

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

I smoked over 2 packs a day. Now down to 0 packs.

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1

#2

2. Dose or Amount	Frequency	Route
#1		
#2		

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

#1 --

#2 --

4. Diagnosis or Reason for Use (Indication)

#1

#2

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Smoking Everywhere Electronic Cigarette

2. Common Device Name
Personal Vapprizer

3. Manufacturer Name, City and State

4. Model #	Lot #
DSE103	n/a
Catalog #	Expiration Date (mm/dd/yyyy)
n/a	
Serial #	Other #
n/a	

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

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MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

DSS

AUG 10 2009

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G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

Phone # E-mail

(b) (6)

2. Health Professional? ☐ Yes ☑ No

3. Occupation
Administrator

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: ☐

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

388266

B5 Describe event or problem continued

has been monitoring me for an unrelated health issue, found my lung CAT scans clearer and my blood test results much better then when I started. Now the REAL adverse effects, which are life threatening to me, is your ban of them. NOT due to public health, but because of the $2.314 BILLION lost in taxes, Big Pharma, and Big Tobacco interests. Your agency is going to be DIRECTLY RESPONSIBLE, for the next round of deaths due to tobacco use. Not only because you decide to ban a safer alternative that your own report PROVES what the electronic cigarette manufacturers claimed ALL ALONG, that they are far safer, but also because you now regulate real cigarettes. So the alterior motive is clear. So, consider this "Adverse Event" the report to the FDA in behalf of the 400,000+ who will die this year alone due to tobacco use.

DSS
AUG 10 2009

U.S. Department of Health and Human Services

Individual Safety Report

CDER

Form Approved: OMB No. 0910-0291, Expires: 10/31/20
See OMB statement on reverse.

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use errors
m - Page 1

FDA USE ONLY
Triage unit sequence # 389335

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	34 Years	☑ Female ☐ Male	300 lb or ____ kg

B. ADVERSE EVENT OR PRODUCT PROBLEM INFORMATION

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)
07/18/2009	08/19/2009

6. Describe Event, Problem or Product Use Error

Experienced a severe headache and nausea. She had to go to sleep for several hours then felt better upon waking.

More

8. Relevant Tests/Laboratory Data, Including Dates

None

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AUG 20 2009

More

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

Nothing other than smoking history of 20 years. Never had this type of reaction to conventional cigarettes

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Green Smoke #Electronic — lowest nicotine cartridge — Green Smoke, Inc.

#2

2. Dose or Amount	Frequency	Route
#1 1 ecig	once	po
#2		

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

#1 07/18/2009 -- 07/18/2009 (one time)

#2 --

4. Diagnosis or Reason for Use (Indication)

#1 to cut back on regular cigarettes

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 ST-1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Green Smoke

2. Common Device Name: electronic cigarette

3. Manufacturer Name, City and State: Green Smoke. Inc manufacturer in china/distributer in florida

4. Model #	Lot #	5. Operator of Device
green smoke #1		☐ Health Professional ☑ Lay User/Patient ☐ Other:
Catalog #	Expiration Date (mm/dd/yyyy)	
Serial #	Other #	

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

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

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

F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

N/A

More

G. REPORTER (See confidentiality section on page 2)

1. Name and Address

(b) (6)

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: ☑

U.S. Department of Health and Human Services

Individual Safety Report

6288763-3-00-01

ARY reporting of product problems and use errors

Page 1

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

Triage unit sequence # 38668/

CDER CDER

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	41 Years	☐ Female ☑ Male	190 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)
07/25/2009	07/28/2009

5. Describe Event, Problem or Product Use Error

After regular use of "smoking everywhere's" electronic cigarettes of both myself and my spouse, jointly experienced light headed feelings of disorientation, slight changes in our vision -depth perception problems, blurred vision- along with headaches and occasional nausea, this only occured after continued use of the smoking everywhere electronic cigarettes, I would est. our period of use to be roughly around 2 or 3 weeks, after discontinued use, our above mentioned symptoms seemed to decrease gradually over time once we resumed smoking of traditional tobacco cigarettes. Personally, I would recommend the the "e-cigarette" industry have a

More

6. Relevant Tests/Laboratory Data, Including Dates

no laboratory or other relevent testing

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More

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

We are both regular smokers of traditional cigarettes, non drinkers, no drug use, problems stated above were not evendent until after roughly a week

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Smoking everywhere e-cigarette High nicotine -16mg- per Smoking everywhere

#2

2. Dose or Amount	Frequency	Route
#1 avg 2 - 3 catridges per day	daily	
#2		

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

#1 07/17/2009 - 07/25/2009

#2 -

4. Diagnosis or Reason for Use (Indication)

#1 Alternative to traditional smoking

#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. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Smoking Everywhere

2. Common Device Name
Electronic Cigarettes

3. Manufacturer Name, City and State
Smoking Everywhere, Inc. 5600 NW 102nd Ave. Suite A
Sunrise, FL 33351 USA

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

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

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)

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JUL 29 2009

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # E-mail
(b) (6)

2. Health Professional? ☐ Yes ☑ No

3. Occupation
Consumer/Non-Health

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: ☑

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

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B5. Describe event or problem continued

much higher accountability for both product testing and quality control.

DSS
JUL 29 2009

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to:
1-800-FDA-0178

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VATCH

sionals of adverse events and product problems

B7 Other relevant history, including preexisting medical conditions continued

or so of use of the smoking everwhere "e-cigarettes"

D55

JUL 29 2009

U.S. Department of Health and Human Services

Individual Safety Report

The FDA Adverse [illegible]

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reporting of
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Page 1 OF 2

1/2

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

FDA USE ONLY
Triage unit sequence # 442536

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 38 Years	☑ Female ☐ Male	185 lb or ____ kg

B. ADVERSE EVENT OR 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)
01/20/2011	01/25/2011

5. Describe Event, Problem or Product Use Error

Im not a doctor, Im a consumer, but couldnt find a consumer reporting page. I recently purchased an e-cigg and oils from a local person that was selling them. I wanted to quit smoking. By the second day, I was very sick. Stomach pains, diarrhea, head throbbing, chest hurting and I could not stay awake, it felt like I had taken a handful of sleeping pills, to the point that walking because difficult, I was hitting the wall and could barely stand. I was told that I had nicotine poisoning and that I need to cut back on the nicotine in the e-cigg. So, I contacted the seller and received oil that was supposed to be half the nicotine

More

6. Relevant Tests/Laboratory Data, Including Dates

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JAN 28 2011
MEDWATCH CTU

More

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

I have no previous conditions, no alcohol use, I do smoke cigarettes. Im not pregnant, Im white -race- and generally healthy other than migraines.

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1	Electronic cigarette 16mg nicotine
#2	

I dont know for sure

2.	Dose or Amount	Frequency	Route
#1	2-3 puffs	every 2-3 hours	
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?	8. Event Reappeared After Reintroduction?
#1 01/18/2011 -- 01/24/2011	#1 ☑ Yes ☐ No ☐ Doesn't Apply	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 to quit smoking	#1 not listed	#1	not available
#2	#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: I didnt get the box. not sure
2. Common Device Name: electronic ciga
3. Manufacturer Name, City and State: unknown. seller would have this. I was told it was from China

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

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

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

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

F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

DSS
JAN 28 2011

More

G. REPORTER (See confidentiality section on page 2)

1. Name and Address
(b) (6)

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

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

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

Individual Safety Report

727151-X-00-02

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MEDWATCH

...ssionals of adverse events and product problems

Internet Submission - Page 2

B5 Describe event or problem continued

amount as the previous oil I had. By that afternoon, all my symptoms had returned. Once I stop, the symptoms go away in about a day or so. Back on the e-cigg, they come back within just a few hours. Same symptoms as above. Then I stopped using it and the symptoms slowly went away in about another day. I called the seller again and was told it must be all in my head because these e-cigga are 100% natural and there is nothing that can hurt you. Im not sure if its nicotine or some other chemical when you "smoke" it, but I was really really sick. My husband wanted to take me to the hospital, but I dont have insurance, so I didnt go. But, it was really bad. Very scary.

DSS

JAN 28 2011

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MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

CDER

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

Internet Submission - Version 1.1

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

FDA USE ONLY

Triage unit 404951

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6)	(b) (6)	☑ Female ☐ Male	165 lb or ____ kg
In confidence	19 Years		

B. ADVERSE EVENT OR PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☐ Product Problem (e.g., defect/malfunction)
☑ 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)
12/05/2009	01/15/2010

5. Describe Event, Problem or Product Use Error

Per packaging and company verbal claim, the e-cigarette bought from Smoke Assist does not contain nicotine is not harmful to the user or those around the user. This is discrepant from the report from the FDA dated 22JUL09 which states e-cigarettes contain nicotine. The e-cigarette was used for less than 7 days, not other problems or events were noted.

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More

6. Relevant Tests/Laboratory Data, Including Dates

N/A

DSS
JAN 19 2010

More

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

History of smoking for 13 years.

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Electronic Cigarette — Smoke Assist

#2

2. Dose or Amount	Frequency	Route
#1 1 puff	PRN	Inhal
#2		

3. Dates of Use (if unknown, give duration) mm/dd/yyyy (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?	8. Event Reappeared After Reintroduction?
#1 12/05/2009 -- 12/12/2009	#1 ☐ Yes ☐ No ☑ Doesn't Apply	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)
#1 smoking cessation
#2

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 UPC 3700107299	#1	INOCIG01
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Smoke Assist
2. Common Device Name: E-Cigarette
3. Manufacturer Name, City and State: unk

OTC

4. Model #	Lot #	5. Operator of Device
	UPC 3700107299990	☐ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☑ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

None

More

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

(b) (6)

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

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

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

U.S. Department of Health and Human Services

Individual Safety Report

6941387-2-00-01

1/3 **CDRH** FDER

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

Submission - Page 1 DQRS

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

FOR FDA USE ONLY
Triage unit
sequence # 390629

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 33 Years	☐ Female ☑ Male	179 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem (e.g., defect/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)
08/26/2009	08/31/2009

5. Describe Event, Problem or Product Use Error

For 1 week I attempted to quite smoking using a device called an e-cigarette or electronic cigarette. The e-cig. that I used is made by Sinless Smoke. A few hours after using the product I notice that I was becoming irritable and moody. That night when I tried to sleep I noticed that I was not able to fall asleep I had strong feelings of paranoia and hallucinations. The symptoms grew worse and worse with my continued use. I thumbed through the user manual and discovered some interesting warnings. The device has an atomizer used to convert the liquid nicotine along the air you are sucking through it to "harmless water vapor" that you exhale.

DSS

SEP 03 2009

More

6. Relevant Tests/Laboratory Data, Including Dates

I researched cigarettes and the Internet and found that each cigarette contains 1.5mg of nicotine per cigarette and the owner's manual stated that each drop of "liquid nicotine or juice as the refer to it." contains 24mg of nicotine per drop and you drop 6 drops into the cartridge each time you

More

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

I am a 2 pack a day cigarette smoker and that is why I used the product.

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☐ No ☑ Returned to Manufacturer on: 08/29/2009 (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Sinless Smoke 24mg
#2

2. Dose or Amount	Frequency	Route
#1 24mg drops 6 at a time	9-12 times a day	po
#2		

3. Dates of Use (if unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 08/18/2009 -- 08/26/2009	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	6. Event Reappeared After Reintroduction?
#1 to stop smoking	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Sinless Smoke
2. Common Device Name: e-cigarette
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: sold over
Serial #	Other #	

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

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

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

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F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

Electronic Cigarette by Sinless Smoke

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone (b) (6) Email (b) (6)

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

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

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

6341367-2-08-02

MEDWATCH

390629

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

B5 Describe event or problem continued

The warning clearly states do not us if atomizer is not functioning properly due to rick of radiation poisoning. I am not an engineer or a scientist so I would not know if it was or was not working properly. My wife stated to me that my positive upbeat energy was non-existent while using the product. I even became depressed as a result of this product. I think the FDA should monitor this product and run their own tests before allowing this product to be sold on shelves.

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SEP 03 2009

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

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

6341307-2-00-03

MEDWATCH

390629

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 3

B6 Relevant tests/laboratory data, including dates (continued)

refill it.

DSS

SEP 03 2009

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

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

Individual Safety Report

7882318-7-00-01

Adverse Event Reporting Program

FORM

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product use errors
ubmission - Page 1

DQR

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

Triage unit sequence # 422887

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	198 lb or ____ kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

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)
09/05/2010	09/16/2010

5. Describe Event, Problem or Product Use Error

Patient quit smoking a 15pack/yr habit in July of 2009 and started using a Joyetech 510 brand electronic cigarette and various flavors of 18mg/ml "eliquid" nicotine juice at that time. 3 months later patient reported significant loss of visual acuity in his right eye -which was already myopic but corrected properly with Rx lenses- and a "haziness" around lighted objects. Patient was diagnosed with the early stages of Posterior Subcapsular Catract in OD and his RX lens was changed to get him back to 20/25 vision in that eye in March of 2009. Over the course of the next 6 months his vision in right eye rapidly deteriorated and on 9/9/10 he was

DSS

SEP 17 2010

More

6. Relevant Tests/Laboratory Data, Including Dates

OD refraction and exam by (b) [redacted] which elucidated the PSC as L4 on 9/9/2010 . Previous exam by optometrist in March of 2009 initially diagnosed the PSC.

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

Patient is caucasian male; Smoking 15pk/year which ended in July 2009. NKDA or other drug use.

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 Dekang/Boge Nicotine eliquid	18mg/ml	Dekang/Boge
#2		

2.	Dose or Amount	Frequency	Route
#1	18mg/ml	daily	Inhal
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 07/02/2009 .. 08/29/2010	#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 nicotine withdrawal	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 none on bottle	#1	none exist
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Joyetech 510 electronic cigarette
2. Common Device Name: electronic cigarette
3. Manufacturer Name, City and State: Joyetech, shanxen. China

4. Model #	Lot #	5. Operator of Device
510	none exists	☐ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☑ Lay User/Patient
Serial #	Other #	☐ Other:

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

8. Is this a Single-use Device ☐ Yes ☑ No

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

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F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER

1. Name and Address

(b) (6)

Phone # E-mail (b) (6)

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

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

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

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B5. Describe event or problem continued

seen by opthamologist (b)(6) and diagnosed with L4 PS cataract and was deemed legally blind in his right eye. Patient will require Lens replacement surgery in that eye to correct this problem-which has been scheduled for 10/26/2010. The only factor that changed in patients life during the time frame of aggressive cataract development was the switch from smoking to the use of electronic cigarette product.

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SEP 17 2010

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Individual Safety Report

7204282-2-00-01

...for VOLUNTARY reporting of ...nts, product problems and ...oduct use errors

CDRH
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Page 1 of 2

Triage unit sequence # 439829

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	74	☐ Female ☑ Male	122 lb or 55.5 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): 11/06/2010

4. Date of this Report (mm/dd/yyyy): 12/19/2010

5. Describe Event, Problem or Product Use Error

(b) (6) age 74 discharged from hospital on 11/2 recovering from pneumonia. Home health nurse visited each day at home to administer antibiotic through PIC line. No problems noted during administration of meds, bp, temp, etc. Upon discharged pulmonologist gave the OK to use electronic cigarette instead of spending $$ on expensive nicotine patches. (b) smoked for 60 years! Got the NJoy electronic cigarette and used that everyday with no visible side effects. The night of 11/6/10, went to bed 9:30 pm, wife checked on him at 10pm and he was fine. Wife went to bed at 11:30 and noticed he was mumbling something. Turned on light and found (b) staring at ceiling saying "I'll be alright in a

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount / Frequency / Route

	Dose or Amount	Frequency	Route
#1	NJoy e-cig	daily	smoke/inhale
#2			

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

#1 11/2 to 11/6 throughout day
#2

4. Diagnosis or Reason for Use (Indication)

#1 Smoking cessation
#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. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: NJoy electronic cigarette

2. Common Device Name: E-cig

3. Manufacturer Name, City and State: NJoy electronic cigarette Traditional Flavor NPro Style "With Nicotine"

4. Model #
Lot #
Catalog #
Expiration Date (mm/dd/yyyy)
Serial #
Other #: UPC 10687 01379

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)

Invanz antibiotic administered by RN through PIC line

G. REPORTER

1. Name and Address

DSS
DEC 30 2010

Name: (b) (6)
Address:
City: (b) (6) State: (b) (6)
Phone # E-mail (b) (6)

2. Health Professional? ☐ Yes ☑ No

3. Occupation: Non-Healthcare Professional

4. Also Reported to:
☐ Manufacturer
☐ User Facility
☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, ...

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem (continued)

minute" Wife and daughter asked him if he was in pain, etc. while the wife called 911. Once on the line with 911, his whole body started to tremble and shake and sound like he was swallowing his tongue. He was using an oxygen concentrator at night and wife made sure that stayed in his nostrils during the "seizure". His eyes remained open during the event. Once the paramedics arrived, "seizure" was over but they rushed him to the nearest ER, put on ventilator and his BP was so low they couldn't take blood samples, so had to give him meds to raise BP. ER staff said CAT scan showed no sign of stroke. Neurologist did spinal tap--results clear. EEG showed brain activity but "slow". MRI was clear. They decided that he must have aspirated something into his lungs while laying down. He was talking to use prior to the trembling! He was ICU for 10+ days and once off the ventilator, he could not talk, eat or swallow. He knew who we were and a feeding tube inserted. After several days swallow test showed he could now eat soft foods and eventually began to talk and eat normal food. Memory was the problem. He had lost 20 years at times but we figured it was due to being in ICU for so long. At this time he is now in a skilled nursing facility/rehab, still having memory problems and may end up being in a nursing home long term because he is considered a safety risk since he cannot walk with the aid of a walker yet. His is a man who was totally ambulatory and active until 11/6. The only difference between being discharged and the "seizure" was the e-cig--had we known there were side effects, he wouldn't have

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

11/7 CAT scan, spinal tap, EEG, MRI

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

Heart attack 1987, another heart attack October 2010 due to pneumonia. Slight stroke 15 years ago only had weak left hand, no other problems. Smoked for 60 years. He is a white male, 74 years of age, retired due to heart condition, being treated for COPD, heart disease prior to 11/6. Smoked 1 pack of filtered cigarettes per day.

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

7045147-8-00-01

The FDA Safety Information and Adverse Event Reporting Program

VOLUNTARY Reporting of se events, product problems and product use errors

Internet Submission - Page 1

DQRS

See OMB statement on reverse.

Triage unit sequence # 432263

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 50 Years	☑ Female ☐ Male	160 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

4. Date of this Report (mm/dd/yyyy): 10/09/2010

5. Describe Event, Problem or Product Use Error

used an electronic cigarette for the first time. Took ten drags in a period of a half an hour. As I was smoking it I started to feel high, dizzy, foggy, and just disconnected mentally. The feeling I got from it was not a good high, but kind of creepy. I also started to feel tired so I went to sleep, got up through out the night and still felt disconnected. In the morning I felt a little better, but still not right. It wasn't until mid day where I felt like my self again. I am wondering if it was the P.G. in the e-cig. that made me feel this way.

More

6. Relevant Tests/Laboratory Data, Including Dates

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

DSS
OCT 13 2010

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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 smokestik -Jet- and. Sic. 13 mg
   #2

2. Dose or Amount	Frequency	Route
#1 10 puffs	1/2 an hour	
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
   #1 10/07/2010 -- 10/07/2010
   #2 --

4. Diagnosis or Reason for Use (Indication)
   #1 want to quit smoking
   #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. Expiration Date
   #1
   #2

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: smokestik JET
2. Common Device Name:
3. Manufacturer Name, City and State: Smokestik Greensboro, NC

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 PRODUCT(S)

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (Confidentiality)

1. Name and Address
   (b) (6)

Phone # E-mail (b) (6)

2. Health Professional? ☐ Yes ☑ No
3. Occupation
4. Also Reported to:
   ☐ Manufacturer
   ☐ User Facility
   ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

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

CDER CDRH

U.S. Department of Health and Human Services

Individual Safety Report

6286527-6-00-01

TARY reporting of product problems and t use errors

Form Approved: OMB No. 0910-0291, Expires: 10/31/09
See OMB statement on reverse.

Page 1 of 1 DQRS

Triage unit sequence # 386384

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6)	(b) (6) 37 YEARS	☐ Female ☑ Male	240 lb or kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
02/22/2009	07/26/2009

5. Describe Event, Problem or Product Use Error

The event that I am reporting is the outrageous scare tactics related to the FDA news release of the hazards of electronic cigarettes. This report was so biased and misleading that you should be ashamed of your agency. After 25 years smoking 2 packs of conventional cigarettes a day, I was able to completely give up tobacco with the use of these devices. By continuing to harass the E-cig community, you are condeming me and others like myself to continued tobaco use. But thats most likely your goal. My personal health has been GREATLY IMPROVED by the use of these devices. Again, you all should be ashamed!

More

6. Relevant Tests/Laboratory Data, Including Dates

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DSS
JUL 28 2009

More

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

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 FDA news release ELECTRONIC CIGARETTES

#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 --	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	6. Event Reappeared After Reintroduction?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (OPTIONAL FOR MANDATORY REPORTS)

1. Name and Address

(b) (6)

Phone # E-mail (b) (6)

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

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

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

Individual Safety Report

CDER

CDRH 386386

DQRS

Rendering Provider: (b) (6) PA-C, (b) (6) **Phone:** (b) (6)
Practice (b) (6)' MEDICAL CTR
Address: (b) (6)

Visit Date: Sunday, July 26, 2009

Patient: (b) (6)
(b) (6)
Medical Record #: **DOB:** (b) (6) **Sex:** Male
home: (b) (6)
Status: Complete. **Billing Provider** (b) (6). **Waiting approval by:** (b) (6)
Visit Last Saved: 07/26/2009 11:37 AM

CC / HPI:

pt states sx started soon after using electronic cigarrette (1)

He presented with cough. It is located in the lung. It is described as constant and worsening @ night. The symptom started 1 weeks ago. Associated signs and symptoms include chills at times, dyspnea at times, sputum production and wheezing.

In addition, he presented with chest congestion. It is described as constant and painful. The symptom started 1 weeks ago. Associated signs and symptoms include sputum production.

Current Medication:

Claritin-D 12 Hour 5 mg-120 mg Tab, 1 Tablet(s), PO, BID and for a total of 30.
Promethazine-DM 6.25 mg-15 mg/5 mL Syrup, 1 Teaspoon(s), PO, Q6-h PRN, for a total of 5 oz and *** PRN cough/congestion ***.
Amoxicillin 500 mg Cap, 1 Capsule(s), PO, Q 8HR, 7 days, for a total of 21, start on July 26, 2009 and end on August 01, 2009.
Proventil HFA 90 mcg/Actuation Aerosol Inhaler, 2 Puff(s), INH, Q4-6h PRN and for a total of 1.
Morphine (Bulk) Misc and Misc.(Non-Drug; Combo Route).

Review of History

I reviewed the medical, medication and drug allergy histories.

ROS:

Constitutional: The patient denied fever.
Ears/Nose/Throat/Neck: The patient denied otalgia and sore throat.
Respiratory: The patient complained of **cigarette smoking** and **cough** but denied asthma.

Vital Signs:

data collected on 07/26/2009 10:11.33 AM by (b) (6)
weight is 228 pounds clothed
height is 5 feet 8 inches
body mass index is 34.66 Kg/m2
temperature is 99.6OF tympanic
respiration rate is 16 breaths per minute quiet
SpO2 is 97% room air
apical heart rate is 80 bpm radial regular
blood pressure at Left Arm while Sitting is 120/70 mmHg

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JUL 28 2009

Constitutional: general appearance, well nourished, well developed, in no acute distress.
Ears/Nose/Throat: otoscopic exam, overall: external auditory canals clear and tympanic membranes clear; and, oral cavity/pharynx/larynx, overall: oral mucosa clear, mobile tongue benign, tonsils benign, oropharyngeal mucosa clear and no masses.
Respiratory: auscultation, left lower lung field: **rhonchi** (slight) and right lower lung field: **rhonchi** (slight); and, respiratory effort/rhythm, no retractions and normal rate.
Cardiovascular: auscultation of heart, rate: regular rate.

Dx:

DSS
JUL 28 2009

386386

(UC) - C - URGENT CARE
(466.0) - C - ACUTE BRONCHITIS

Rx:

pt states she can take phenergan/promethazine cough syrup
Amoxicillin 500 mg Cap, 1 Capsule(s), PO, Q 8HR, 7 days, for a total of 21, start on July 26, 2009 and end on August 01, 2009.
Promethazine-DM 6.25 mg-15 mg/5 mL Syrup, 1 Teaspoon(s), PO, Q6-h PRN, for a total of 5 oz and *** PRN cough/congestion ***.
Proventil HFA 90 mcg/Actuation Aerosol Inhaler, 2 Puff(s), INH, Q4-6h PRN and for a total of 1.

Services Performed:

(99203) URGENT CARE VISIT-NEW
(94760) MEASURE BLOOD OXYGEN LEVEL (pre 97%, post 99%)
(94640) AIRWAY INHALATION TREATMENT (xopenex 1.25)

Plan:

A return visit is indicated in 2 days if symp persist. He was advised to be on a Regular diet.

Plan Comment:

Quit smoking, discontinue electronic cigarette, rewst/fluids

(b) (6)

DSS
JUL 28 2009

Individual Safety Report

6735384-7-08-01

Adverse Event Reporting Program

...ARY reporting of ...roduct problems and ...r use errors ...ns - Page 1 DQRS

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

Triage unit sequence # 418943

1. Patient Identifier (b) (6) — In confidence
2. Age at Time of Event, or Date of Birth: 37 (b) (6)
3. Sex: ☐ Female ☑ Male
4. Weight: 310 lb or ___ kg

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): 05/18/2010
4. Date of this Report (mm/dd/yyyy): 05/19/2010

5. Describe Event, Problem or Product Use Error

electronic cigarette purchased from esmoke.net was advertised as "not having ANY carcinogens" and "all cartridges free from US materials" I visited the head location and saw materials being shipped in from China for use in the product and the e-cigarette had chemical taste to it and malfuunctioned. This can be a serious health threat to the people seeking benefits from this product. FDA needs to investigate ASAP

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More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

DSS
MAY 20 2010

More

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

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

1. Name, Strength, Manufacturer (from product label)
#1 e-cigarette www.esmoke.net
#2

2. Dose or Amount | Frequency | Route

	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use (if unknown, give duration) Inserts (or best estimate)
#1 --
#2 --

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

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

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

	6. Lot #	7. Expiration Date	8. NDC # or Unique ID
#1			
#2			

OTC

1. Brand Name: www.e-smoke.net
2. Common Device Name: electronic cigarette
3. Manufacturer Name, City and State: esmoke.net in Lakewood NJ

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

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

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

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

Product names and therapy dates (exclude treatment of event)

More

1. Name and Address
(b) (6)

Phone (b) (6)

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

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

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

7

B5 Describe event or problem continued

quality control over the e-liquids. I'm just opposed to such a strong statement based on such little real evidence.

CDER

U.S. Department of Health and Human Services

Individual Safety Report

Tr
Ac 0208518-4-09-01

ARY reporting of
roduct problems and
use errors
m - Page 1

DQRS

Form Approved: OMB No. 0910-0291, Expires: 10/31/09
See OMB statement on reverse.

FOR FDA USE ONLY
Triage unit sequence # 386387

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	183 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)
01/04/2009	07/23/2009

5. Describe Event, Problem or Product Use Error

I bought the e-cigerette for the purpose of stopping smoking. When using the device I would become very dizzy to the point that I would have to sit down. I have also starting having a very high white blood count that no one can find a reason for. Also after stopping the use of the product I have had a continued cough. I feel these are all problems caused by the product.

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6. Relevant Tests/Laboratory Data, Including Dates

I have been having numerous blood tests over the past 9 months with white counts as high as 15,000.

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

Smoking, have devoloped a serve fatty liver and diabetes is very hard to control now. For reasons unknown.

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
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 --	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	9. Event Reappeared After Reintroduction?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	8. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Smoke Everywhere.com
2. Common Device Name: [redacted]
3. Manufacturer Name, City and State: Unknown

4. Model #	Lot #	5. Operator of Device
Unknown	Unknown	☐ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☑ Lay User/Patient
Unknown	01/01/2009	☐ Other:
Serial #	Other #	
Unknown		

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)

(b) (6)

Phone: (b) (6) Email: (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Administrator	☐ Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐		☐ User Facility ☐ Distributor/Importer

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

CDRH CDER CBER DORS

U.S. Department of Health and Human Services

Individual Safety Report

6288812-7-08-01

TARY reporting of product problems and ct use errors

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

Page 1

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Triage unit sequence # 386388

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	27 Years	☐ Female ☑ Male	180 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)
07/23/2009	07/21/2009

5. Describe Event, Problem or Product Use Error

I have been using electronic cigarettes for about two monthes now and have experienced no adverse effects. I enjoy the experience, and I am confident it is 100 times safer than smoking regular cigarettes. I just hope the FDA realizes the health benefits of such a product and the money that can be saved on healthcare in the long term. If electronic cigarettes are banned and regular tobacco cigarettes are still allowed to be sold it will be totally hypocritical of the FDA to allow such a dangerous and harmful product to be sold. Please study and regulate the e-cig ingredients to protect our health, but do not isue an outright ban of a great

6. Relevant Tests/Laboratory Data, Including Dates

n/a

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

former tobacco smoker. Now totally tobacco free.

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
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (if unknown, give duration) from/to (or best estimate)	8. Event Abated After Use Stopped or Dose Reduced?
#1 --	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	9. Event Reappeared After Reintroduction?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	10. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: electronic cigarette
2. Common Device Name:
3. Manufacturer Name, City and State: totally wicked eliquid

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 (Will be kept confidential)

1. Name and Address
(b) (6)

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: ☐

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

Individual Safety Report

6288812-7-00-02

MEDWATCH

386388

...professionals of adverse events and product problems

Internet Submission - Page 2

B5 Describe event or problem continued

product that can help millions of Americans stop smoking, or continue to "vape" in a safe way.

DSS

JUL 28 2009

MEDWATCH

Individual Safety Report

6286523-1-00-01

Adverse Event Reporting Program

...ARY reporting of ...product problems and ...r use errors CDER DQRS

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

Trade unit sequence # 386385

Attorney submission - Page 1

A PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ 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)
07/23/2009	07/24/2009

5. Describe Event, Problem or Product Use Error

The event I would like to report is one of great significance in my life. I QUIT SMOKING! I did so by using electronic cigarettes. I get to enjoy the parts of smoking that I like, without ALL of the harmful byproducts. Do I want FDA regulation to make sure the products are as safe as they can be? YES Should you ban these outright when so many people stand to benefit? NO Stop this witch hunt and work with suppliers.

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6. Relevant Tests/Laboratory Data, Including Dates

DSS
JUL 28 2009

More

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

I smoked at least 1 pack of cigarettes a day for 13 years, and now I'm free!

More

C PRODUCT AVAILABILITY

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

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

D SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Health E-Cigarette Marlboro flavor -Health E-Cigarette medium
#2

2.	Dose or Amount	Frequency	Route
#1	18 mg	regularly	po
#2			

3. Dates of Use (if unknown, give duration) from/to (or best estimate)
#1 07/09/2009 -- 07/24/2009
#2 --

4. Diagnosis or Reason for Use (Indication)
#1 I smoked and hated it.
#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. Expiration Date
#1
#2

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

9. NDC # or Unique ID

E SUSPECT MEDICAL DEVICE

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

F OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G REPORTER See confidentiality section on back

1. Name and Address
(b) (6)

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

2. Health Professional? ☐ Yes ☑ No
3. Occupation: Consumer/Non-Health
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: ☐

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

1/2 CDER

Individual Safety Report

6201344-I-00-01

Adverse Event Reporting Program

VOLUNTARY reporting of events, product problems and product use errors

DQRS

Submission - Page 1 CDER

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

FOR FDA USE ONLY

Triage unit sequence # 386497

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 34 Years	☑ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR PRODUCT USE 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)
07/27/2009	07/27/2009

5. Describe Event, Problem or Product Use Error

No adverse reaction. Am using this avenue to voice my disgust with the FDA and its announcement on e-cigs. Talk about biased!!!!! So, I guess there truly is an adverse reaction being posted here...to the FDA!!!! The e-cig isn't being targeted to children...the online sites specifically state this. And guess what?? They're are a lot of adults who want flavors that you all think are there to be attributed to "marketing to children." As a smoker of nearly 30 years, I'm thrilled to have found the e-cig. It's helped me quit cigs...something even Chantix couldn't accomplish. Actually, I'm not opposed to the FDA wanting to exert some

More

6. Relevant Tests/Laboratory Data, including Dates

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

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   #1
   #2

2. Dose or Amount	Frequency	Route
#1		
#2		

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

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

5. Lot #
   #1
   #2

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

7. Expiration Date
   #1
   #2

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: e-cig
2. Common Device Name: ELECTRONIC CIGARETTE
3. Manufacturer Name, City and State

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

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☑ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCT

Product Names and therapy dates (exclude treatment of

D55

JUL 29 2009

More

G. REPORTER (Confidential Section of Form)

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: ☐

FORM FDA 3500 (9/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

6291344-X-00-02

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

B5 Describe event or problem continued

quality control over the e-liquids. I'm just opposed to such a strong statement based on such little real evidence.

DSS
JUL 29 2009

U.S. Department of Health and Human Services

MI Individual Safety Report

The FD/ ... reporting of
Adverse ... t problems and
errors

6645566-0-00-01

Page 1 DQRS

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

Triage unit sequence # 412045

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified (In confidence)		☐ 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) 03/18/2010

5. Describe Event, Problem or Product Use Error

E-cigarettes are being smoked in areas where smoking of cigarettes is prohibited by state law, without consideration for the health of nonsmokers. I am aware that FDA has discovered TSNAs, glycols, and nicotine in the E-liquid of these devices. I would like to outline a research program to investigate the claims that E-cigarettes can be smoked anywhere. It is obvious that E-cigarettes emit an aerosol when puffed. Aerosol in the outdoor air -PM2.5- is a regulated air pollutant with no known threshold for acute and chronic effects on the cardiovascular system. It may also contain ultrafine particles, and does contain VOCs of various

More

6. Relevant Tests/Laboratory Data, Including Dates

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More

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

DSS
MAR 19 2010

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCTS

1. Name, Strength, Manufacturer (from product label)
#1 E-cigarettes
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

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

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. Expiration Date
#1
#2

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name
E-cigarettes

3. Manufacturer Name, City and State

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

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional? ☑ Yes ☐ No

3. Occupation Biomedical Engineer

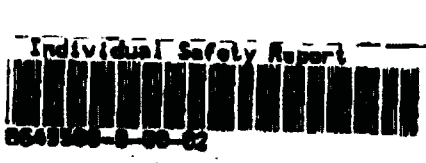
4. Also Reported to:
☐ Manufacturer
☐ User Facility
☐ Distributor/Importer

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

FORM FDA 3500 (6/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

4/2V45

Individual Safety Report



MEDWATCH

...ionals of adverse events and product problems
... Submission - Page 2

B5 Describe event or problem continued

sorts, including nicotine, which is a known toxin. It is also known that air pollution affects people differently depending upon their health status and sensitivity. The hypothesis being advanced by proponents is that there are no acute or chronic health effects or air pollution impacts if these devices are used in currently smoke-free areas. So a research program would start by collecting multiple samples of each of the 2 dozen or so brands currently being marketed and analyzing the E-liquids in them. Next, multiple tests would be run on the devices when they are smoked under controlled circumstances in an experimental chamber to determine emission factors for each of the components of toxicological interest, including carcinogenic potency. In this manner, the standard mass-balance model can be used to predict their concentrations in occupied spaces. Next, panels of healthy nonsmokers and sensitive nonsmokers would be employed to test the odor, irritation, and cardiorespiratory impacts of exposure to E-cigarette vapor, using standard butanol wheel, eye-blink, pulmonary function, and heart rate variability tests. This would allow public policy to be based on science, rather than speculation. Of course, such studies would involve multi-million dollar research grants and multidisciplinary researchers involved. Then the peer-reviewed and journal-published data would be reviewed by impartial expert panels of national and international agencies. I submit that this would be the intelligent way to make a public health policy decision involving exposure of infants, children, elderly persons, and those with cardiorespiratory conditions to products of currently unknown composition and unknown interaction with the hundreds of existing air pollutants in indoor air. Until this is done, it is only prudent to keep E-cigarettes out of smoke-free zones. (b) (6)

DSS

MAR 19 2010

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

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

Individual Safety Report

7228144-X-00-01

CURIL

.UNTARY reporting of
nts, product problems and
roduct use errors DQRS

Page ___ of ___ CDER

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

FDA USE ONLY

Triage unit sequence # 441134

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
In confidence	(b) (6)	☐ Female ☒ Male	179 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)

5. Describe Event, Problem or Product Use Error

HAD SORE LUNGS AND SORE THROAT

P.S THEY DO NOT HAVE BROCHER ON PRODUCT

6. Relevant Tests/Laboratory Data, Including Dates

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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 EZ SMOKE

#2

2. Dose or Amount	Frequency	Route
#1 4. M		
#2		

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

#1 9,10

#2 10,10

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 LUNG - SORE

#2 THROAT - SORE

A. 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 E PUFFER INTERNATION

2. Common Device Name EZ PUFFER

3. Manufacturer Name, City and State

800 STEELES AV CANADA

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

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

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

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

☐ Yes ☒ No

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

DSS
JAN 12 2011

G. REPORTER (See confidentiality section on back)

1. Name and Address

Phone (b) (6) E-mail

2. Health Professional? ☐ Yes ☒ No

3. Occupation RETIRED

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: ☐

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.

U.S. Department of Health and Human Services

Individual Safety Report

#628377-1-00-01

CDRH

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

DQRS

Submission - Page 1 ...ER

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

FDA USE ONLY
Triage unit sequence #: 426941

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6)	(b) (6) 57 Years	☐ Female ☑ Male	220 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)
08/14/2010	08/14/2010

5. Describe Event, Problem or Product Use Error

I WANT TO REPORT ADVERSE EFFECTS OF E CIGS. I WENT ON LINE AND BLOGGED THESE OVER AND OVER AGAIN BEFORE I TRIED THEM. I SMOKED THEM FOR 2 MONTHS WHICH I THOUGHT WAS BETTER FOR ME THAN CIGS. I WENT IN FOR ROUTINE PHYSICAL AND DOCTOR ASKED WHEN I HAD HAD A HEART ATTACK I SAID NEVER. HE THAN HAD ME DO A STRESS TEST. CAME OUT OR. RECENTLY HAD BELLS PALSY. THE MORAL IS ALL TIMES INTO THE DOCTOR MY RESTING HEART RATE WAS AT 40 BEATS A MINUTE. ALL THREE TIMES. SINCE I STARTING REAL CIGS AGAIN MY HEART BEAT IS BACK TO 65 PER MINUTE. I CAN ONLY CONCLUDE THAT THE E CIG ARTIFICIALLY REDUCED MY HEART RATE. ALSO WONDER IF IT COULD HAVE

More

6. Relevant Tests/Laboratory Data, including Dates

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More

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

DSS
AUG 16 2010

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 --	#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	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: SMOKE TIP
2. Common Device Name: E CIG
3. Manufacturer Name, City and State: CHINA

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

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

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

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

F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

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

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail

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

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

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

Individual Safety Report
0026377-0-00-02

426941

WATCH
professionals of adverse events and product problems
ternet Submission - Page 2

B5 Describe event or problem continued

CONTRIBUTED TO BELLS PALSY -NO WAY TO KNOW-. THE OTHER THING HAPPENING WAS A CONSTANT LOOSE BOWEL SYNDROME. I AM WRITING THIS BECAUSE THE BLOGS ON INTERNET MUST ALL BE CONTRIVED BY THE E CIG MANUFACUTURES BECASUE I COULD FIND NO ADVERSE EFFECTS ON LINE MAY CONTACT ME AT (b) THANK YOU HOSPITALIZTION WAS FOR THE BELLS PALSY

DSS

AUG 16 2010

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

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

MI [redacted] 4968772-4-00-01

KY reporting of duct problems and product use errors

DQRS

The FDA Adverse Event Reporting Program

(Internet) Submission - Page 1

FDA USE ONLY
Triage unit sequence # 424631

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 25 Years	☐ Female ☑ Male	160 lb or ___ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., device 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)
07/19/2010	07/20/2010

5. Describe Event, Problem or Product Use Error

After using a e-cig, felt very sick and dizzy then started sweating badly. felt the need to go to sleep early and while in bed started to vomit.

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MEDWATCH CTU

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6. Relevant Tests/Laboratory Data, Including Dates

DSS
JUL 21 2010

More

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

smoking

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

	Name	Strength	Manufacturer
#1	E-Cigarette	1mg	Health E-Cigarette
#2			

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 07/15/2010 -- 07/19/2010	#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 smoker	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	8. NDC # or Unique ID
#1 none	#1	none
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

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: ☑

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

CDRH CDER

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

Internet Submission - Page 1/2 DQRS

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

FDA USE ONLY
Triage unit sequence # 453131

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 52 Years	☑ Female ☐ Male	165 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)*
05/04/2011	05/09/2011

5. Describe Event, Problem or Product Use Error

Use of the e-cigarette and possible link to pleurisy. Pt has been a 2+ pack a day cigarette smoker for the past 30 years. Pt decided to quit, and was using the e-cigarette thinking it was a safe alternative and a way to help quit smoking. Pt had been using the e-cigarette for about 3 months, without using any "real" cigarettes. Pt started to have sharp pains in chest for a couple of days when pt would breath in and out. Pt went to my PCM and was dignosed with pleurisy and fluid in lungs. The e-cigarette uses water vapor.

More

6. Relevant Tests/Laboratory Data, Including Dates

MRI 05/04/2011

More

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

NKDA, White female, occasional alcohol use. 2+ pack a day smoker for past 30 years. About 3 months ago quit using "real" cigarettes and started

More

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 E-cigarette UKN UKN
#2

2. Dose or Amount	Frequency	Route
#1 aprox 2 cartriges	per day	po
#2		

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 02/01/2011 -- 05/09/2011	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 smoking cessation aid
#2

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

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

9. NDC # or Unique ID
unk

E. SUSPECT MEDICAL DEVICE

1. Brand Name: ukn
2. Common Device Name: e-cigarette
3. Manufacturer Name, City and State: ukn

4. Model #	Lot # ukn	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:

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MAY 11 2011
MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address
(b) (6)

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

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

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

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

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

B7. Other relevant history, including preexisting medical conditions continued

using e-cigarette.

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

CDRH

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

FDA USE ONLY
Triage unit sequence # 43536/

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) In confidence	51	☑ Female ☐ Male	102 lb or 46.4 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/02/2010	

5. Describe Event, Problem or Product Use Error

I read an article on line about how to quit smoking with an electronic cigarette. In this article the writer explained how she quit and how good she felt smoking this e-cig. There was a link to buy one for shipping costs, only $4.95. You got a months supply with the order, to try it. I clicked on the link that took me to an order now page at Directecig.com. There was advertising on this page to buy other flavors and herbs but other than that, it was fill out your info and we'll send it to you. I received my ecig around Oct.8 but couldn't use it until I charged it. I had to mess with the battery and charger for 20 minutes to get it to start charging every time I tried.

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.)*

I have been a smoker for 30+ years.

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: Directecig.com
Strength: 16mg
Manufacturer: Directecig.com

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 10/08/2010	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 10/13/2010	#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 # #1 / #2	7. Expiration Date #1 / #2
	9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Directecig.com

2. Common Device Name: e-cig

3. Manufacturer Name, City and State: Directecig.com 2338 immokalee rd. #419 naples, florida 34110-1445

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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

1. Name and Address

Name: (b) (6)
Address
City: (b) (6) State: (b) (6)

Phone #	E-mail
	(b) (6)

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

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

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

After charging it, I put the nicotine "filter" on the end. There's no taste to this. Only an after taste that lingered for hours. The article said that the ecig looked, tasted and satisfied your craving just like a real cigarette without all the harmful chemicals. At first I thought I just needed to get used to it being different, but I asked my adult son to try it and he had no idea it was supposed to be menthol and told me several hours later he still had the after taste. I was still craving a real cigarette and bought some. And smoking them didn't really cover the taste from the ecig. I got so frustrated with it, I put it in the recycling. On Oct. 20th, I received an email from directecig saying my order was shipped and the cost was $99.95. I emailed right away and told them I didn't order anything. That's when they informed me that I had signed up for some sort club and that they were going to ship me more cartridges every month. In the course of emails that followed, they sent me a copy of their terms and conditions page that I was unaware of. I immediately opted out on line when I found it. I looked at my bank account on line and there was a hold for $99.95 on my account which disappeared, then reappeared the following monday. I tried to track the fedex number they sent me with invalid coming up. I got a package by usps and sent it back. I filed a complaint with the BBB in which I said this tasted tainted (my first realization). That's when I fished the ecig out of the recycling (the battery makes it harder to recycle it) and came to your website. If you would like to look into this,

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)*

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

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

Internet Submission - Page 1

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

FDA USE ONLY
Triage unit sequence # 448962

A. PATIENT INFORMATION

1. Patient Identifier: (In confidence
2. Age at Time of Event, or Date of Birth: (b) (6)
3. Sex: ☐ Female ☑ Male
4. Weight: _____ 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
☐ 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): 09/01/2009
4. Date of this Report (mm/dd/yyyy): 03/28/2011

5. Describe Event, Problem or Product Use Error

Rash around your face and started to get worse Constant constipation Lungs started hurting-pain increased in 2009/2010- The way the product is designed you inadvertently swallow the ejuice which causes burning in throat When you charge the batteries and take them off the charger it looks like battery acid forming. The only thing you can do is throw the batteries away. Replacement parts aren't any good.

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6. Relevant Tests/Laboratory Data, Including Dates

-last chest xray was 3-4 months ago which show spot in left lung which has been there

More

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

Diagnosed with emphysema back in 1996

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 E-Cigarette Njoy
#2 NCig -on battery-

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 09/01/2009 -- 03/21/2011
#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
2. Common Device Name
3. Manufacturer Name, City and State

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

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail

2. Health Professional? ☐ Yes ☐ No
3. Occupation
4. Also Reported to: ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

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

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

CDRH CDER

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

Internet Submission - Page 1

DQR

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

FDA USE ONLY
Triage unit sequence # 453617

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	21 Years	☐ Female ☑ Male	185 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)*
05/11/2011	05/12/2011

5. Describe Event, Problem or Product Use Error

the e-cigarette product is leaking large amounts of nicotine. i took a few puffs and it leaked all in my mouth causing an adverse reaction including, redness and swelling of lips, and red dots on hands.

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

Caucasian male, smoker

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Smoke Free High Smokefree Electronic
#2

2.	Dose or Amount	Frequency	Route
#1	unkown	as needed-	Inhal
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 05/09/2011 -- 05/12/2011	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply
4. Diagnosis or Reason for Use *(Indication)* #1 quit smoking ade	8. Event Reappeared After Reintroduction? #1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 none	#1	none
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Smoke Free
2. Common Device Name: Gold Edition
3. Manufacturer Name, City and State: Smoke free www.smokefreeonline.com

OTC

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address
(b) (6)

Phone #	E-mail (b) (6)

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

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

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

U.S. Department of Health and Human Services

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The FDA Safety Information and Adverse Event Reporting Program

CDRH CDER

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

Internet Submission - Page 1 of 2 DQRS

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

FDA USE ONLY
Triage unit sequence # 456315

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6)	(b) (6)	☑ Female ☐ Male	120 lb or ____ kg
In confidence	24 Years		

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/01/2011	06/10/2011

5. Describe Event, Problem or Product Use Error

I quit smoking cigarettes about a week ago. I decided to make it easier on myself I would try the electronic cigarette it has only been a week and im already seeing problems with my health. Im having nose bleeds and coughing just as much as I was with my full flavored menthol cigarettes I smoked for 15yrs! I was a heavy smoker around a pack or more a day so I thought it was just my lungs trying to repair but I have noticed I cough more after I use the e cigarette and it leaves a strange chemical taste in the back of my throat. As for the nose bleeds im not sure how to explain the reason im getting them but I never really had problems with

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Inhale
#2 Electronic cigarette

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 06/01/2011 -- 06/10/2011
#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 Help quit smoking
#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: Inhale
2. Common Device Name: Electronic cigarette
3. Manufacturer Name, City and State

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

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

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

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address
(b) (6)

Phone # ____ 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: ☐

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For VOLUNTARY reporting by health professionals of adverse events and product problems

Internet Submission - Page 2

B5. Describe event or problem continued

nose bleeds in my past I havr had about 5since I have started using the e cigarette just 1WEEK ago!

U.S. Department of Health and Human Services

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The FDA Safety Information and Adverse Event Reporting Program

CDRH DQRS

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

Internet Submission - Page 1 CDER

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

FDA USE ONLY
Triage unit sequence # 457981

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	38 Years	☐ Female ☑ Male	170 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/27/2011	06/27/2011

5. Describe Event, Problem or Product Use Error

Pt stated was smoking a lithium powered e-cigarette while he was driving and it exploded in his mouth, causing 2nd degree burns to his face, mouth and injury to his left eye. He was treated in our ER and transferred to a burn center in Bakersfield, CA.

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

38 year old white male, no meds, no significant PMH, no allergies, smokes approx. 5 cigarettes per day, no alcohol use.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*		
#1 electronic cigarette	unk	puresmoker.com
#2 lithium batteries	cr123a 3.0v	titanium innovations

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 06/26/2011 -- 06/26/2011	#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 smoking cessation	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

5. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 unk	#1	none
#2 unk	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: titanium innovations lithium batteries and
2. Common Device Name: e cigarette
3. Manufacturer Name, City and State: purchased online

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address
(b) (6)

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

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

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

CDER DQRS

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

Internet Submission - Page 1

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

FDA USE ONLY
Triage unit sequence # 190048

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 53 Yea	☑ Female ☐ Male	183 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)*
	08/02/2011

5. Describe Event, Problem or Product Use Error

GreenSmoke and e-cigarette company uses propylene glycol in their product. After using the product I have had a productive cough - sputum greenish yellow. I do not have a upper respiratory infection -checked at doctor- and my allergies are under control. The product causes coughing after use and for hours after.

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AUG 03 2011
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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.)*

Hypothyroidism Hypomagnesaemia Hyperaldosteronism Hypertension/Hypotension Migraine without aura Chronic Fatigue Syndrome Fibromyalgia Chronic Pain - all over GERD Stroke Quite smoking 4 months ago

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 GreenSmoke o%
#2

2.	Dose or Amount	Frequency	Route
#1	unknown - not stated	5 times a day	respiratory (inhalation)
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 06/30/2011 – 08/01/2011 (6 weeks)
#2 –

4. Diagnosis or Reason for Use *(Indication)*
#1 for real cigarette sensation
#2

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

6. 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 A33008	#1 05/20/2013	A33008
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: GREENSMOKE
2. Common Device Name: E-CIGARETTE
3. Manufacturer Name, City and State: China

4. Model #	Lot # A33008	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)* 05/20/2013	☐ Health Professional ☑ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*
None Stopped usage

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	Other Health Professional	☑ Manufacturer ☑ User Facility ☑ Distributor/Importer

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

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

U.S. Department of Health and Human Services

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The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence #: US-FDA-193335

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 8 Mon	☑ Female ☐ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
08/14/2011	09/27/2011

5. Describe Event, Problem or Product Use Error

Our child developed what appeared to be a spasm/dystonic reaction while on vacation in the UK - manifested as a recurrent, rhythmic right shoulder shrug. This faded after return to the US, but reappeared after a few weeks. I believe this is due to secondhand exposure to nicotine vapor generated by an electronic cigarette. Her father uses an e cigarette but had not, prior to her adverse reaction, used it indoors or near her. While on vacation in London, he began using the device inside our hotel room, because of questionable safety on the streets during the riots. On return to the US, he became more comfortable with its apparently safe

6. Relevant Tests/Laboratory Data, Including Dates

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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: e cigarette 1 1

#2:

2. Dose or Amount	Frequency	Route
#1:		
#2:		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1: --	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2: --	#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	#1:
#2:	#2:

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

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

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

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

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

B5. Describe event or problem continued

us and gradually increased the proximity and duration of its use near our infant. After discontinuing its use indoors, our daughter's spasm has not recurred. She has had no other symptoms of nicotine toxicity to my knowledge.

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US-FDA-193335

For VOLUNTARY reporting by health professionals of adverse events and product problems

Internet Submission - Page 6

[redacted]

FDA Comments

	Drug	Manufacturer	Dose	Unit	Route	Frequency Dosage	Interval	Unit	Is Concomitant

	Diagnosis for Use	Start Date	End Date	Duration	Unit

FDA Comments:

```
wilsonj: |*********|  2011-09-28-09.02.26  |*********|
USFDAMWVOLUNTARY_193335_7187_20110927.xml
Route To: AERS      :  Electronic
Route To: DQRS      :           : Paper
Route To: Misc.     :           : Paper
Send copy to Center or Tobacco Products
```

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

[redacted]

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

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
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The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

FDA USE ONLY

Triage unit sequence # US-FDA-194500

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event, or Date of Birth: (b) (6) 53 Yea
3. Sex: [x] Female [ ] Male
4. Weight: 185 lb or _____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*: 10/14/2011

4. Date of this Report *(mm/dd/yyyy)*: 10/17/2011

5. Describe Event, Problem or Product Use Error

Spent the day using a Nicotek Metro menthol electronic cigarette in my effort to quit smoking real cigarettes. The next morning I noticed that my throat and chest ached and felt like they might possibly have been burned by the vapor. I have been suffering since with shortness of breath and difficulty breathing. This was after only one day of use. I have not used it since.

6. Relevant Tests/Laboratory Data, Including Dates

None yet.

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

Have smoked Salem menthol cigarettes for approx. 35 years but have quit.

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Metro menthol electronic cigaret 1/8% Nicotek
   #2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 10/13/2011 – 10/14/2011
   #2 –

4. Diagnosis or Reason for Use *(Indication)*
   #1 As a substitute for real cigarettes
   #2

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

6. Lot #
   #1
   #2

7. Expiration Date
   #1
   #2

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Metro
2. Common Device Name: electronic cigarette
3. Manufacturer Name, City and State: Nicotek, LLC 4860 Ward Road, Wheat Ridge, CO 80033

4. Model #	Lot #	5. Operator of Device
Metro menthol 1.8%		[ ] Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	[ ] Lay User/Patient
Serial #	Other #	[x] Other: consumer

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 [x] 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? [ ] Yes [x] No
3. Occupation: Consumer/Other non Health professional
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: [ ]

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Diagnosis for Use	Start Date	End Date	Duration	Unit

FDA Comments:

```
WILSONJ: |*********|  2011-10-18-08.46.25  |*********|
USFDAMWVOLUNTARY_194500_8181_20111017.xml
Route To: AERS      :  Electronic
Route To: DQRS      :           : Paper
Route To: CDRH      :           : Paper
I need a copy for Tobacco Center
```

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

Return to Form

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

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

Internet Submission - Page 1

FDA USE ONLY

Triage unit sequence # US-FDA-200017

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 27 Yea	☑ Female ☐ Male	115 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)*
01/21/2012	01/22/2012

5. Describe Event, Problem or Product Use Error

I was using an electronic cigarette when i started having chest pain then an extremelly rapid heartbeat. I called an ambulance and was transported to the hospital. The cigarette brand was N-Joy.

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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 Njoy electronic cigarette n/a NJoy
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration)* from/to *(or best estimate)*
#1 01/19/2012 -- 01/21/2012
#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

6. 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 na	#1	na
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name NJoy
2. Common Device Name electronic cigarette
3. Manufacturer Name, City and State Scottsdale.arizona

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)

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: ☐

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

U.S. Department of Health and Human Services

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The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # US-FDA-199894

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 51 Yea	☐ Female ☑ Male	182 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)*
12/26/2011	01/19/2012

5. Describe Event, Problem or Product Use Error

Tried to use a Mistic brand full-flavored e-cigarette in order to stop smoking tobacco cigarettes. Did not like the taste, so I ordered a Blu Cig starter kit, using the vanilla cartridges. I did not like the Blu e-cig either, so I ordered a Halo G6 starter kit. With this type of e-cig, you must add smoke juice to the cartomizer, in order to keep the unit operational. The flavors that Halo offered were terrible, but I tried one called Prime 15, which is suppose to be their best seller. This flavor tasted like peanut butter which I disliked very much. I ordered some smoke juice from a company in California, called Tasty Vapors. These are made

6. Relevant Tests/Laboratory Data, Including Dates

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

I am allergic to dust, but that is the only allergen that I am aware of. I do smoke cigarettes and was using about a pack a day. I no longer consume any alcohol.

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 Atomic Cinnacide 24 mg. nicotine Tasty Vapor US
#2 Ultimate Vanilla 24 mg. nicotine Tasty Vapor US

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 12/26/2011 -- 01/07/2012
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 smoking cessation
#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: Halo G6 Starter Kit
2. Common Device Name: e-cigarette
3. Manufacturer Name, City and State: Halo Company

4. Model #	Lot #	5. Operator of Device
G6		☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☑ Lay User/Patient
Serial #	Other #	☐ 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)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Other non Health professional	☐ Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐		☐ User Facility ☐ Distributor/Importer

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

B5. Describe event or problem continued

ith both Propylene Glycol and Vegetable Glycerin. I tried to use their most popular flavor, which was Atomic Cinnacide and it caused my throat to get very sore and raw. I stopped using that flavor and continued to use the smoke juice in their vanilla flavor and a blend called Geoff's Blend, which tasted like Juicy Fruit gum. A short time after I discontinued using the Atomic Cinnacide flavor, I began having flu like symptoms. After these symptoms manifested themselves, I began having sinusitis and sinus infection symptoms. It has been three weeks today, since I became ill and I am still not completely well.

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The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # US-FDA-200018

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	40 Yea	☑ Female ☐ Male	155 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)*
01/19/2012	01/22/2012

5. Describe Event, Problem or Product Use Error

E-Cigarettes. Shortness of breath and extreme bloating.

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6. Relevant Tests/Laboratory Data, Including Dates

NA

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

obviously a smoker, but I do not have this reaction to regular cigarettes.

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 E-liquid 32mg KOV

#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration)* from/to *(or best estimate)* 9 days

#1 01/09/2012 -- 01/19/2012

#2 --

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

#1 smoking cessation

#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 NA	#1	NA
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Knockout Vapor

2. Common Device Name: E-Cigarettes

3. Manufacturer Name, City and State: Rio Rancho, New Mexico

4. Model #	Lot # NA	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)

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

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

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

U.S. Department of Health and Human Services

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The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # US-FDA-201229

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	35 Yea	☑ Female ☐ Male	135 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: 01/25/2012 *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - Initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	02/11/2012

5. Describe Event, Problem or Product Use Error

I work with (b)(6) and the CEO has explained that the nicotine cartridges the company manufactures and sells in the United States contain (b)(4) as an ingredient aside form the liquid nicotine and propylene glycol. Although he will not disclose the specific ratio contents of the cartridges, he has explained that during his many trips to the manufacturing factories in (b)(4) China, he knows that the process involving which involves the building and filling of cartridges is likely tainted with (b) . My understanding is that the mixture contained in the flavor cartridges (b)(6) sells in the US contains a

6. Relevant Tests/Laboratory Data, Including Dates

(b customers have been reporting a series of side effects derived from the use of (b electronic cigarettes. While company management has explicitly instructed (b)(6) customer service to tell all customers reporting side effects that those are the result of stopping to smoke traditional cigarettes.(Cont...)

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

Most users of the (b product often report severe effects after use, whether regular or irregular. which includes, headaches and migraines, allergies -manifesting by means of hives, itchiness, asthma-, heavy motion sickness

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 (b) (
#2

2.	Dose or Amount	Frequency	Route
#1	0 Mg to 18 ng	Daily	Oral
#2			

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

4. Diagnosis or Reason for Use *(Indication)*
#1 Smoking Cessation
#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 ALL
#2

7. Expiration Date
#1
#2

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

9. NDC # or Unique ID
N/A

E. SUSPECT MEDICAL DEVICE

1. B (b)(6)
2. Common Device Name Electronic Cigarette
3. Manufacturer Name, City and State (b)(6)

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)*

(Electronic Cigarettbs, Smoking Cessation Aid -As claim(Cont...)

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

1. Name and Address
(b)(6)

E-mail

(b)(6)

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

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

B5. Describe event or problem continued

mixtur of propylene glycol, liquid nicotine and other flavorings. However (b)(6) (b)(6) assists and follows the manufacturing process which both the e-cig batteries and accessories and flavor cartridges go through, has reported himself that he would never use the product because he is aware of the contents which include (b)(4) . He has explained that it is also present because (b)(4) My concerns are not unfounded. Most users of the (b product often report severe effects after use, whether regular or irregular. which includes, headaches and migraines, allergies -manifesting by means of hives, itchiness, asthma-, heavy motion sickness, vomiting, stomach unrest, diarrhea, shortness of breath and palpitations . I have become increasingly concerned that the product our company sells is, in its current state, not suitable for human use or consumption. Especially after hearing the comments and explanations from (b)(6) regarding the product and its contents. He clearly explained that because the FDA has no jurisdiction over the products, that at the current stage, the manufacturing standards from China are so unregulated that the contents of the products will go undetected for the moment. The main argument behind this rationale is that his profits will continue to soar tremendously with such low manufacturing costs but huge profits. The company is currently importing the products through highly illegal means in the US, from (b)(4) Many of the products do not have the correct specifications or labels and many shipments have been detained and confiscated because of non-compliance. Furthermore, without knowledge of its employes, the company has been using the names and social security number of many employees to import shipments of tons of products in order to avoid customs screening. This recently resulted in US customs detaining and questioning one of said employe during her holiday travels and she had her passport confiscated upon return to the US -despite being a US citizen- as has been issued several notices by US customs. (b)(6) is willfully putting consumers at great danger and violating not only custom and import laws, but is also KNOWINGLY selling a potentially poisonous product in great quantities. The company currently makes about $(b)(4) sales per day through its website and it distributing (b)(4) to masses without their knowledge. The long term damage is at this point unknown but will have grave consequences for consumers, according to the (b)(6). (b)(6) oversees the manufacturing process of (b) products from our various factories in (b)(4) . He oversees the conceptualization of all our products / batteries as well as the making of flavor cartridges and their contents. He has clearly stated that he has no 100% knowledge of what actually goes into the manufacturing of the flavor cartridges and that their contents have not passed minimal safety tests assessed in China, by China standards and much less by US, FDA and US Customs Standards. In addition, the majority of products imported by the company do not meet the standards required for imports in terms of labeling and safety. While the company DOES have chocking hazards warnings on its instruction manuals, the company was contacted less than 2 weeks ago regarding the death of a baby under 1yr old, whom choked on a (b flavor cartridge. (b)(4) I believe that this company is currently a massive threat to the public because of its practices, faulty products and toxic ingredients. And that it does so knowingly at this point for the sole reason that the monetary benefits are huge while blatantly saying that it can do so without any impact and regulation from the FDA. My concerns are founded, especially since seeing a huge rise in people's complains regarding our products and the side effects they are experiencing. While it may not be clear at this point what the long terms effect of (b)(4) will be on consumers, it most certainly will become evident within a few years. And thekidney and liver damages resulting from the use of (b)(6) electronic cigarettes will be far greater than that of other toxins used and allowed by the FDA on concumer products. Again, this was stateded by (b)(6) whom oversees the design, manufacturing and production of (b products.

B6. Relevant tests/laboratory data, including dates continued

(b) (6) has epressed that he knows it is most likely due to the chemicals and toxins in the cartridges of the (b) (6) product contents, not disclosed to consumers. Yet he instructs his staff to be convincing regarding the fact that any symptoms expreiences should be associated with stopping smoking traditional cigarettes. He himself, as a heavy smoker, stated -which is on tape- that he would never use his own (b products because he knows the true contents of the products which includes (b) (4) and other highly toxic chemicals which he will not disclose on the product content but have been clea

B7. Other relevant history, including preexisting medical conditions continued

vomiting, stomch unrest, diarrhea, shortness of breath and palpitations . (b) customers have been reporting a series of side effects derived fro

F. Other (Concomitant) medical products

d in the (b) (6) website. Clearand obvius non-compliance not to advertise as a smoking cessation product-

H6. FDA Comments

Drug	Manufacturer	Dose	Unit	Route	Frequency Dosage	Interval	Unit	Is Concomitant

Diagnosis for Use	Start Date	End Date	Duration	Unit

FDA Comments:

WALKERC: |*********| 2012-02-13-11.01.54 |*********|
USFDAMWVOLUNTARY_201229_13950_20120211.xml
Route To: CDRH : : Paper

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # US-FDA-202088

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	35 Yea	☑ Female ☐ Male	145 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
02/25/2012	02/25/2012

5. Describe Event, Problem or Product Use Error

I've been smoking the E-cigarette for about a month now, when I first started smoking these e-cigarettes I noticed a wheezing sound every time after I inhaled. This lasted for about almost 2 weeks. I don't hear the wheezing noise anymore, how ever lately I have noticed I get a little dizzy with nausea and disoriented after inhaling, I didn't pay much attention to it, but today after inhaling the e-cigarette I felt extreme nausea, dizziness, tingling throughout my body accompanied with weakness, disorientation and trouble breathing. I told my husband that I didn't feel good. I woke to find myself on the bathroom floor and my husband calling

6. Relevant Tests/Laboratory Data, Including Dates

None

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

Allergic to Keflex Medication. Occasional smoker and drinker. No other major health issues that I know of.

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 E-Cigarette Strawberry-High Green Smart Living

#2

2.	Dose or Amount	Frequency	Route
#1	HIGH	Daily	Respiratory (inhalation)
#2			

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

#1 01/19/2012 – 02/25/2012

#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 Personal use

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 9201112280	#1 12/28/2012
#2	#2

9. NDC # or Unique ID

S808

E. SUSPECT MEDICAL DEVICE

1. Brand Name Green Smart Living

2. Common Device Name Electronic Cigarette

3. Manufacturer Name, City and State 324 S 400 W Suite 150 Salt Lake City, UT 84101

4. Model #	Lot #	5. Operator of Device
S801 & S808	9201112280 for refil	☐ Health Professional
Catalog # S801 & S808	Expiration Date (mm/dd/yyyy) 12/28/2012	☐ Lay User/Patient
Serial # Not sure	Other # S801 & S808	☑ Other Personal Use

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)

Green Smart Living Rechargeable Super Electronic Cigarette Model# S801 & Refuel Now refills 5 pack Model# S808

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

Phone # E-mail

(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Other non Health professional	☐ Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑		☐ User Facility ☐ Distributor/Importer

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

B5. Describe event or problem continued

m name, continued to feel disoriented, but this time having difficulty speaking. I was slurring...I had passed out. I was having difficulty moving my body as it felt extremely heavy, my hands and feet felt as if I were having a tremendous body spam causing my hands to curl in, as seen on patients with Cerebral Palsy. It was EXTREMELY scary specially since I do not really have health issues. I am not sure if this was caused by the e-cigarette, but I do not have any other explanation to this mornings incident.

H6. FDA Comments

Drug	Manufacturer	Dose	Unit	Route	Frequency Dosage	Interval	Unit	Is Concomitant

Diagnosis for Use	Start Date	End Date	Duration	Unit

FDA Comments:

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WILSONJ: |*********|  2012-02-27-10.00.31  |*********|
USFDAMWVOLUNTARY_202088_14727_20120226.xml
Route To: AERS      :  Electronic
Route To: DQRS      :           : Paper
Route To: CDRH      :           : Paper
Need Copy for CTP
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