The following message accompanies all responses 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.
I have chemical irritation per my doctor throughout my mouth the tongue and throat and now it is going down my throat.
Hello,

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

[NAME 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 a test and found an antihistamine in her bloodstream 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 [DATE 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
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Internet Submission - Page 1

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

A. PATIENT INFORMATION
1. Patient Identifier
   - Name:
   - Age at Time of Event, or Date of Birth:
   - Sex: Female
   - Weight: 180 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. Check all that apply:
   - 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: ____________________________
   - Disability or Permanent Damage: __________
   - Life-threatening: __________
   - Congenital Anomaly/Birth Defect: __________
   - Hospitalization (initial or prolonged): __________
   - Other Serious (important) Medical Events: __________
   - Required Intervention to Prevent Permanent Impairment/Damage (Devices): __________

3. Date of Event (mm/dd/yyyy)
   - 01/01/2009

4. Date of this Report (mm/dd/yyyy)
   - 04/22/2013

5. Describe Event, Problem or Product Use Error

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

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
6. Relevant Tests/Laboratory Data, Including Dates

- EKG normal, cardiac enzymes normal, drug test was positive with marijuana.

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

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

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
- Yes
- No
- Returned to Manufacturer on: ________________________

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (form product label)
   - Regular E cigs
   - Sample E cigs

2. Dose or Amount
   - The highest dosage:

3. Dates of Use (If unknown, give duration) (mon, or best estimated)
   - 01/01/2011

4. Diagnosis or Reason for Use (Indication)
   - I was a current smoker

5. Event Altered After Use
   - Stopped or Dose Reduced?
     - Yes
     - No
     - Doesn't Apply

6. Event Reappeared After Reintroduction?
   - Yes
   - No
   - Doesn't Apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name
   - E cigs

2. Common Device Name
   - E cigs

3. Manufacturer Name, City and State
   - I purchased in

4. Model #

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

E. SUSPECT MEDICAL DEVICE

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

- E cigs

G. REPORTER (See confidentiality section on back)

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

2. Health Professional
   - Yes
   - No

3. Occupation
   - Nurse

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.
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 polypropylene glycol -sp-. They

no allergies, Type II diabetic, peripheral neuropathy, No alcohol use in over 20 yrs. Bipolar
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.
I was a cigarette 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 nicotine than the Lozenges 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 lozenges 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.
# Electronic Cigarettes

**Scented Oils**

*Got my asthma, allergy act up, I couldn't breathe, severe congestion.*

## A. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>1. Patient Identifier</th>
<th>2. Age at Time of Event or Date of Birth</th>
<th>3. Sex</th>
<th>4. Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Image]</td>
<td>59 (6)</td>
<td>Female</td>
<td>[Image]</td>
</tr>
</tbody>
</table>

## B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

- **Check all that apply:**
  - [ ] Adverse Event
  - [ ] Product Problem (e.g., defects/malfunctions)
  - [ ] Product Use Error
  - [ ] Problem with Different Manufacturer of Same Medicine

- **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)

- **Date of Event**: 4-11-2013

- **Date of this Report**: [mm/dd/yyyy]

## E. SUSPECT MEDICAL DEVICE

- **Brand Name**
- **Model #**
- **Lot #**
- **Operated by Device**
- **Operator of Device**
  - [ ] Health Professional
  - [ ] Lay User/Patient
  - [ ] Other

## C. PRODUCT AVAILABILITY

- **Product Available for Evaluation?**
  - [ ] Yes
  - [ ] No
  - [ ] Returned to Manufacturer on: [mm/dd/yyyy]

## D. SUSPECT PRODUCT(S)

- **Name, Strength, Manufacturer (from product label)**
  - **Electronic Cigarettes**
  - **Scented Oils**

## 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**
   - **Name:** [b (b) (6)]
   - **Address:** [b (b) (6)]

2. **City:** [b (b) (6)]
3. **State:** [b (b) (6)]
4. **ZIP:** [b (b) (6)]
5. **Phone #:** [b (b) (6)]
6. **E-mail:** [b (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:**
For VOLUNTARY reporting of adverse events, product problems and product use errors

Internet Submission - Page 1

A. PATIENT INFORMATION
1. Patient Identifier
   [b]
   In confidence

2. Age at Time of Event, or Date of Birth:
   [b] (6)

3. Sex
   [b] Female
   [b] Male

4. Weight
   [b] 163 lbs
   [b] kg

B. AVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. Adverse Event
2. Product Problem (e.g., defect/infunction)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine

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

3. Date of Event (mm/dd/yyyy)
   [b] 05/29/2013

4. Date of this Report (mm/dd/yyyy)
   [b] 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

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)
   [b] Yes
   [b] No
   [b] Returned to Manufacturer on: [mm/dd/yyyy]

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   [b] White Rhino
   [b] liquid

2. Dose or Amount
   Frequency
   Route

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

4. Diagnosis or Reason for Use (Indication)

5. Event Abated After Use Stopped or Dose Reduced?
   [b] Yes
   [b] No
   [b] Doesn't Apply

6. Event Reappeared After Reintroduction?
   [b] Yes
   [b] No
   [b] Doesn't Apply

7. Lot #

8. Expiration Date

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE
1. Brand Name
   [b] White Rhino

2. Common Device Name
   [b] White Rhino

3. Manufacturer Name, City and State
   [b] White Rhino

4. Model #
   [b] na

5. Catalog #
   [b] na

6. Expiration Date (mm/dd/yyyy)
   [b] na

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

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

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] (b) (6)

2. Phone
   [b] (b) (6)

3. E-mail
   [b] (b) (6)

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

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: [b]
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (b) (6)
2. Age at Time of Event, or Date of Birth: (b) (6)
3. Sex: Female
4. Weight: 145 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. 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):
   05/02/2013
4. Date of this Report (mm/dd/yyyy):
   05/15/2013
5. Describe Event, Problem or Product Use Error:
   Super Vapeur 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 Apt on 5-15-13
   Antibiotics & 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 Vapeur E Cig

2. Dose or Amount
   - Frequency
   - Route

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

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

5. Event Abated After Use Stopped or Dose Reduced?
   - #1 Yes
   - #2 No

6. Event Reappeared After Reintroduction?
   - #1 Yes
   - #2 No

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
   - CTU
3. Manufacturer Name, City and State
4. Model #
5. Lot #
6. Catalog #
7. Expiration Date (mm/dd/yyyy)
8. Serial #
9. Other #

E. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

F. REPORTER (See confidentiality section on back)
1. Name and Address
2. Health Professional?
3. Occupation
   - Housewife
4. Also Reported to: Manufacturer
   - User Facility
   - Other:

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.
**A. PATIENT INFORMATION**

1. Patient Identifier (b) (6) _____
2. Age at Time of Event, or Date of Birth: (b) (6) _____
3. Sex: male
4. Weight: 310 lb

**B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR**

1. Adverse Event: yes
2. Product Problem (e.g. defects/malfunctions): yes
3. Product Use Error: no
4. Problem with Different Manufacturer of Same Medicine: yes

**C. PRODUCT AVAILABILITY**

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

**D. SUSPECT PRODUCT(S)**

1. Name, Strength, Manufacturer (from product label): Nictomate premium electronic ciga
2. Dose or Amount: 2 or 3 tips daily
3. Dates of Use (if unknown, give duration) from/to (e.g. last used): 05/26/2013 - 05/28/2013
4. Diagnosis or Reason for Use (Indication): stop smoking aid
5. Event Altered After Use Stopped or Dose Reduced?
   - Yes
   - No
6. Event Reappeared After Redoing?
   - Yes
   - No
7. Expiration Date: n/a
8. NDC # or Unique ID: none

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name: Nictomate premium electronic cigarette
2. Common Device Name: electronic cigarette
3. Manufacturer Name, City and State: Nictomate, 746 Spring Hill Farm Dr. Manchester, MO 63021
4. Model #: none
5. Operator of Device: health professional
6. If Implantated, Give Date: n/a
7. If Exploded, Give Date: n/a
8. Product names and therapy dates (exclude treatment of event): just the product and regular tobacco tips

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

1. Name and Address: (b) (6) 
2. Phone #: (b) (6) 
3. E-mail: 
4. Also Reported To:
   - Manufacturer: yes
   - User Facility: no
   - Distributor/Importer: no
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box: yes

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

**U.S. Department of Health and Human Services**

**MEDWATCH**

The FDA Safety Information and Adverse Event Reporting Program

**Internet Submission - Page 1**
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!
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 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.
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. **Patient Identifier**
   - **Self**
   - **Identifier**
   - **Date of Birth:**
   - **Sex:**
     - Female
     - Male
   - **Weight:**
     - lb
     - kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

1. **Adverse Event**
2. **Product Problem** e.g. defects/malfunctions
3. **Product Use Error**
4. **Problem with Different Manufacturer of Same Medicine**
5. **Outcomes Attributed to Adverse Event**
   - Death:
   - Life-threatening:
   - Hospitalization - initial or prolonged:
   - Other Serious (Important Medical Events):
   - Required Intervention to Prevent Permanent Impairment/Death (Devices):
6. **Date of Event**
7. **Date of this Report**

8. **Event Altered After Use**
   - Stopped or Dose Reduced?
   - Repeated After Reintroduction?

9. **Lot #**
10. **Expiration Date**

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer**
   - Nicotine Cartridge 14mg
   - A Clean Cigarette

2. **Dose or Amount**
3. **Frequency**
4. **Route**

5. **Date of Use**
   - Initial to (or best estimate):
   - Reference:

6. **Diagnosis or Reason for Use**
   - Help to Stop Smoking

7. **Expiration Date**

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 #**
5. **Lot #**
6. **Catalog #**
7. **Expiration Date**
8. **Serial #**
9. **Operator of Device**
   - Lay User/Patient
   - Other:

10. **If Implanted, Give Date**
11. **If Implanted, Give Date**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER

1. **Name and Address**
2. **Phone**
3. **E-mail**
4. **Occupation**
5. **Other Reported to:**
6. **If you do NOT want your Identity disclosed to the manufacturer, place an "X" in this box:**

C. PRODUCT AVAILABILITY

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

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

A. PATIENT INFORMATION
1. Patient Identifier [b] (6)
   Age at Time of Event, or
   Date of Birth:
   [b] (6) 
   3. Sex 
   [b] Male
   or
   [b] Female
   In confidence

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

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

2. Outcomes Attributed to Adverse Event
   [b] Death:
   [b] Yes
   [b] No
   (mm/dd/yyyy)
   Disability or Permanent Damage
   Life-threatening
   Congenital Anomaly/Birth Defect
   Hospitalization - initial or prolonged
   Other Serious (Important) Medical Events
   [b] Yes
   [b] No
   Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)
   [b] (6)

4. Date of this Report (mm/dd/yyyy)
   [b] (6)

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 first few months
   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

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.

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

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

C. PRODUCT AVAILABILITY

1. Product Available for Evaluation? [b] Yes
   [b] No
   [b] Returned to Manufacturer on:
   (mm/dd/yyyy)

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

3. Occupation
   [b] Consumer/Non-Health
   [b] Other

4. Also Reported to:
   [b] Yes
   [b] No

5. If you do NOT want your identity disclosed
to the manufacturer, place an "X" in this box:
   [b] Yes
   [b] No

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.
beggad 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.
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.
MedWatch
The FDA Safety Information and Adverse Event Reporting Program
Internet Submission - Page 1

Part A: Patient Information

(b) (6)
1. Patient Identifiers
   (Confidential)

2. Age at Time of Event, or Date of Birth:
   40 Yea

3. Sex
   □ Male
   □ Female
   [ ] Other

4. Weight
   □ 155 lb
   □ 0 kg
   [ ] Other

Part H: Adverse Event, 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
   □ Disability or Permanent Damage
   □ Life-Threatening
   □ Congenital Anomaly/Defect
   □ Hospitalization - initial or prolonged
   □ Other Serious (Important Medical Events)
   □ Required Interventions to Prevent Permanent Impairment/Damage
   (Devices)

3. Date of Event (mm/dd/yyyy)
   01/19/2012

4. Date of this Report (mm/dd/yyyy)
   01/23/2012

5. Describe Event, Problem or Product Use Error
   E-Cigarettes. Shortness of breath and extreme bloating.

For Voluntary Reporting of Adverse Events, Product Problems and Product Use Errors

Part D: Suspect Product(s)

1. Name, Strength, Manufacturer (from product label)
   a. E-liquid 32mg KOV

2. Dosage or Amount

3. Dates of Use (if relevant, give duration) and/or (if relevant) smoking cessation
   □ 01/09/2012
   □ 01/19/2012

4. Diagnosis or Reason for Use (Specify)
   □ Stop smoking

5. Event Abated After Use
   □ Yes
   □ No
   □ Do not apply

6. Event Reappeared After Reintroduction
   □ Yes
   □ No
   □ Do not apply

7. Lot #
   □ NA

8. Expiration Date
   □ NA

Part 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 #

5. Catalog #

6. Serial #

7. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other

8. If Implant, Give Date (mm/dd/yyyy)

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

10. Is this a Single-Use Device that was Reprocessed and Reused on a Patient?
    □ Yes
    □ No

11. If Yes to Item No. 10, Enter Name and Address of Reprocessor

Part F: Other (Concomitant) Medical Products

Product names and therapy dates (excluding treatment of event)

Part G: Reporter

1. Name and Address (b) (6)

2. Phone # (b) (6)

3. Health Professional?
   □ Yes
   □ No

4. Also Reported to:
   □ Manufacturer
   □ User Facility
   □ Other:

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

RECEIVED
JAN 23 2012
MEDWATCH CTU

(Confidentiality section on back)
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
For VOLUNTARY reporting of adverse events, product problems and product use errors

A. PATIENT INFORMATION

1. Patient Identifier
   - Last Name: [Redacted]
   - First Name: [Redacted]
   - Middle Initial: [Redacted]
   - Date of Birth: 55 Years
   - Gender: Female
   - Weight: 130 lb
   - Height: 5 ft

B. ADVERSE EVENT/PRODUCT PROBLEM OR ERROR

Check all that apply:
1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
   - Product Use Error
   - Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
   - Death: (mm/dd/yyyy)
   - Disability or Permanent Damage
   - Congenital Anomaly/Birth Defect
   - Hospitalization - initial or prolonged
   - Other Serious (Important Medical Events)
   - Required Interventions to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 12/01/2012
4. Date of this Report (mm/dd/yyyy): 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 goes hoarse. Within a day my sinuses become infected. Please help get these bad products off the market!!! I can't get my husband to quit using these hazardous products, he will only quit when they are banned.

6. Relevant Tests/Laboratory Data, Including Dates

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

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

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
   - Yes
   - No
   - Returned to Manufacturer on: [Redacted]

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (must product label)
   - All types of e-cigarettes
   - Various
   - #2

2. Dose or Amount
   - Frequency
   - Route

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

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

5. Event Avoided If Use Stopped or Dose Reduced?
   - Yes
   - No
   - Doesn't Apply

6. Event Reappeared After Reintroduction?
   - Yes
   - No
   - Doesn't Apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name
   - Various

2. Common Device Name
   - E-cigarette

3. Manufacturer Name, City and State
   - Various

4. Model #
5. Serial #

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

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

Phone #: [Redacted]
E-mail: [Redacted]

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: [Redacted]

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

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier
   
2. Age at Time of Event, or Date of Birth:
   
3. Sex:
   - [ ] Female
   - [ ] Male

B. ADVERSE EVENT PRODUCT PROBLEM OR ERROR

1. Adverse Event:
   - [ ] Yes
   - [ ] No

2. Outcomes Attributed to Adverse Event:
   - [ ] Death
   - [ ] 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 (Device)

3. Date of Event (mm/dd/yyyy)
   - [ ] 01/13/2013

4. Date of this Report (mm/dd/yyyy)
   - [ ] 01/13/2013

5. Describe Event, Problem or Product Use Error:

12 hours after inhaled a 5mg vanilla dose of electronic cigarette, 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 cigarette 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

6. Relevant Tests/Laboratory Data, Including Dates:
   - [ ] None

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

   Smoking: Camel Previous e-cigarette brand JLS line, blueberry - no reactions incurred during 1 week prior to the rash.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA):
   - [ ] Yes
   - [ ] No
   - [ ] Returned to Manufacturer on (mm/dd/yyyy)

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.
A. PATIENT INFORMATION

1. Patient Identifier # (e.g., name, address, phone)
   - [ ] Male
   - [ ] Female

B. ADVERSE EVENT PROBLEM OF 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
   (Include 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)

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)
   [ ] Electronic Cigarettes

2. Route
   - [ ] Inhalation

3. Date(s) of Use: [ ] Unknown, [ ] From/to (or Best Estimate)
   - [ ] mm/dd/yyyy

4. Diagnosis or Reason for Use (Indication)
   - [ ] mm/dd/yyyy

5. Event Altered After Use
   - [ ] Stopped or Does Reduced?
   - [ ] Yes  [ ] No  [ ] Doesn't Apply

6. Lot #
   - [ ] mm/dd/yyyy

7. Expiration Date
   - [ ] mm/dd/yyyy

8. NDC # or Unique ID
   - [ ] mm/dd/yyyy

E. SUSPECT MEDICAL DEVICE

1. Brand Name
   [ ] Electronic Cigarettes

2. Common Device Name
   [ ] Electronic Cigarettes

3. Manufacturer Name, City and State
   - [ ] mm/dd/yyyy

4. Model #
   - [ ] mm/dd/yyyy

5. Operator of Device
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] Other:

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

G. REPORTER (See confidentiality section on back)

1. Name and Address

Phone #

E-mail

H. Also Reported To:

1. [ ] Health Professional
2. [ ] Consumer/Non-Health
3. [ ] Manufacturer
4. [ ] User Facility
5. [ ] Distributor/Importer

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

can you check into electronic ciggaretts causing pleurisy

i magically have it after starting electronic ciggaretts
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 Kilias, 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 / renelynnch

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

http://latimesblogs.latimes.com/nationnow/2012/02/electronic-cigarette-explodes-mans-mo... 2/16/2012
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.

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 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 assess 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.

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

**A. PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>Patient Identifier (b)</th>
<th>Age at Time of Event, or Date of Birth (b) (6)</th>
<th>Sex</th>
<th>Weight</th>
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<td>(in confidence)</td>
<td>(b) (6)</td>
<td>Female</td>
<td>220 lbs</td>
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**B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR**

Check all that apply:

1. Adverse Event ☑
2. Product Use Error ☐
3. Product Problem (e.g., defects/malfunctions) ☐

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) ☐

Date of Event (mm/dd/yyyy): 03/10/2012

Date of this Report (mm/dd/yyyy): 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

**C. PRODUCT AVAILABILITY**

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

☑ Yes ☐ No ☐ Returned to Manufacturer on:

---

**D. SUSPECT PRODUCT(S)**

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

   Njoy

   #1

   #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) Event

   #1 -- --

   #2 -- --

4. Diagnosis or Reason for Use (Indication)

   smoking cessation

   #1

   #2

5. Event Started After Use Stopped or Dose Reduced?

   ☑ Yes ☐ No ☑ Doesn't Apply

   #1

   #2

6. Event Reappeared After Reintroduction?

   ☑ Yes ☐ No ☑ Doesn't Apply

   #1

   #2

7. Lot #

   #1

   #2

8. Expiration Date

   #1

   #2

9. NDC # or Unique ID

---

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

---

**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

Product names and therapy dates (exclude treatment of event)

   - elavil
   - tramadol
   - hydrocodone
   - carbamazepine
   - klonopin

---

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

1. Name and Address

   (b) (6)

2. Health Professional? ☑ Yes ☐ No

3. Occupation

4. Also Reported to:

   ☑ Manufacturer ☐ User Facility ☐ Distribution/Import

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑ Yes ☐ No

---

**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.
### FDA Comments:

<table>
<thead>
<tr>
<th>Diagnosis for Use</th>
<th>Start Date</th>
<th>End Date</th>
<th>Duration</th>
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**FDA Comments:**

- Wilson: [******] 2012-04-13-07.47.07 [******]
- USPDMVOLUNTARY_205900_17216_26120412.xml
- Route To: Misc. Paper
- Need copy for CTP

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 of adverse events, product problems and product use errors

Internet Submission - Page 1

**A. PATIENT INFORMATION**

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<th>Item</th>
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<td>Sex</td>
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<tr>
<td>Weight</td>
<td>122 lb</td>
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**B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR**

Check all that apply:

1. Adverse Event  
2. Product Problem (e.g., defect/abnormalities)  
3. Product Use Error  
4. Problem with Different Manufacturer of Same Medicines

**C. OUTCOMES ATTRIBUTED TO ADVERSE EVENT**

- Death: (mm/dd/yyyy)  
- Disability or Permanent Damage: (mm/dd/yyyy)  
- Incapacity or Permanent Impairment: (mm/dd/yyyy)

**D. SUSPECT PRODUCT(S)**

1. Name, Strength, Manufacturer (from product label)
   - Lava, extra strength, Made in USA

2. Dose or Amount  
3. Route  
4. Frequency  
5. Date of Use (if unknown, give duration from/to or best estimate)

**E. SUSPECT MEDICAL DEVICE**

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

**F. OTHER CONCUMITANT MEDICAL PRODUCTS**

Product names and therapy dates (exclude treatment of event)

**G. REPORTER**

(See confidentiality section on back)

**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.
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
Every since I began using the ProSmoke electronic cigarette, my gums have started bleeding. I was wondering if you had other reports of this happening?
### H6. FDA Comments

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<th>Unit</th>
<th>Route</th>
<th>Frequency Dosage Interval Unit</th>
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**FDA Comments:**

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

Mail to: MEDWATCH or FAX to:
5600 Fishers Lane 1-800-FDA-0178
Rockville, MD 20852-0787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
For VOLUNTARY reporting of adverse events, product problems and product use errors
Internet Submission - Page 1

A. PATIENT INFORMATION
1. Patient Identifier: [Confidential]
2. Age at Time of Event, or onset: [Confidential]
3. Sex: Male or Female
4. Weight: [Confidential]

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. Adverse Event
2. Drug Expiration
3. Ongoing Problem (e.g., persistent symptoms)
4. Product Use Error
5. Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
(Choose all that apply)
- Death
- Disability or Permanent Damage
- Health-threatening
- Congenital Anomaly/Birth Defect
- Hospitalization - severe 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
On 06/07/2012, patient reported coughing after using an e-cigarette or Electronic Nicotine Delivery System - ENDS - product distributed by www.acleancigarette.com. The nicotine concentration was 24mg - 2.4% 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 confirm that the product contained vegetable glycerine which has been implicated in pulmonary problems - see article by McCauley.

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
- Yes
- No

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (Form product label)
- Electronic cigarette - ENDS -
2. Dose or Amount
3. Frequency
4. Route
5. Event Alleviated After Use
   - Stopped or Dose Reduced?
6. Event Reappeared After Reintroduction?

7. Date of Use (if unknown, give duration from to (or best estimate))
8. Event Alleviated After Use
   - Stopped or Dose Reduced?

9. Date of this Report (mm/dd/yyyy)

E. SUSPECT MEDICAL DEVICE
1. Brand Name: acleancigarette.com
2. Common Device Name: Electronic nicotine delivery system - ENDS -
3. Manufacturer Name, City and State: acleancigarette.com

4. Model #
5. Lot #
6. Operator of Device
7. If Implanted, Give Date (mm/dd/yyyy)
8. If Implanted, Give Date (mm/dd/yyyy)

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

G. REPORTER (See confidentiality section on back)
1. Name and Address
2. Phone: [Confidential]
3. E-mail: [Confidential]
4. Also Reported to:
- Manufacturer
- User Facility

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

L. Chest 2012;141-4::1110-113-. The distributor also admitted that an undisclosed number of clients had reported "allergic reactions" -no details- to the product.
hyperlipidemia, Barrett's Esophagitis, GERD, Diabetes, type 2, Obesity, Chronic lower back pain.
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 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.

See section 5

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
Yes ☐ No ☐ Returned to Manufacturer on (mm/dd/yyyy) ☐

FORM FDA 3500 (B/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 pain. Due to the timing of the surgery, I attributed those 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 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.
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...
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 assumed 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.
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 my body was reacting to the absorption of a rather significant quantity of nicotine. It was assumed 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 tests 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.
For VOLUNTARY reporting of adverse events, product problems and product use errors

**A. PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>(b) (6)</th>
<th>3</th>
<th>Sex</th>
<th>4 Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>185 lb</td>
</tr>
</tbody>
</table>

**B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR**

Check all that apply

1. **Adverse Event**
2. **Product Problem** (e.g. defects/malfunctions)
3. **Product Use Error**

Outcomes Attributed to Adverse Event

- [ ] 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)

Date of Event (mm/dd/yyyy)

07/13/2012

Date of Report (mm/dd/yyyy)

07/13/2012

Describe Event, Problem or Product Use Error

I was using "premium" electronic cigarettes, and began finding when I coughed up phlem it contained blood; these were 15mg nicotine, this had happened before but I did not associate it with e-cigarettes but I found when I stopped using them the blood disappeared from my phlem I think there is a direct correlation between users... further I feel FDA should investigate and advise the public if these e-cigs are safe or not.

**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, /product label |
| (b) (6) | premium electronic cigarette 15mg nicotine premium # cigarette |

**E. SUSPECT MEDICAL DEVICE**

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

Made in China

**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

Product names and therapy dates (exclude treatment of event)

**G. REPORTER**

(See confidentiality section on back)

**H. FDA USE ONLY**

Tragic event sequence

B7. Other relevant history, including preexisting medical conditions continued

blood i would note i am not currently smoking
After using a e-cig, felt very sick and dizzy then started sweating badly. Felt the need to go to sleep early and in bad started to vomit.

RECEIVED
JUL 21 2010
MEDWATCH CTU

DSS
JUL 21 2010

smoking
**Electronic Cigarette Case**

**Event Description:**

Electronic cigarette was purchased from MyCig.com as a supposed safer 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 headache, dizziness. Symptoms persisted for at least 24 hours. This experience was repeated several times, with E-liquid containing less nicotine to rule out nicotine overdose. Even a tiny amount of this product.

**Product Information:**

- **Brand Name:** MyCig Technology Inc. Ltd.
- **Container/Device Name:** E-cig, E-cig, E-cig
- **Container/Device Name:** MyCig Technology Inc. Ltd. No. 142 Danahan M. Rd. Ind. 1 Ph. High-Tech Building Citi Ekibang 335300 China

**DSS**

**Submission:**

- **Date:** SEP 02 2008
- **MedWatch CTU:**

**Other Relevant History:**

- Smoking prior to exposure.
- **Yes**
- **No**

**Return to MedWatch or: (optional)**

**Product Exposure:**

- **Yes**
- **No**

**Product Description:**

- **Yes**
- **No**

**Product Name:**

- **MedWatch**
- **MEDWATCH**

**DSS**

**Submission:**

- **Date:** SEP 02 2008

**Other Relevant History:**

- Smoking prior to exposure.

**Yes**

**No**

**Return to MedWatch or: (optional)**

**Product Exposure:**

- **Yes**
- **No**

**Product Description:**

- **Yes**
- **No**

**Product Name:**

- **MedWatch**
- **MEDWATCH**

**DSS**

**Submission:**

- **Date:** SEP 02 2008

**Other Relevant History:**

- Smoking prior to exposure.

**Yes**

**No**

**Return to MedWatch or: (optional)**

**Product Exposure:**

- **Yes**
- **No**

**Product Description:**

- **Yes**
- **No**

**Product Name:**

- **MedWatch**
- **MEDWATCH**
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.
I am writing with a concern about Njoy electronic cigarettes. I purchased Njoy in late February 2010 in an 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
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 vapor 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)
Individual Safety Report

Adverse event reporting of

Patient Information

1. Patient Name:
2. Age:
3. Sex: Male
4. Weight: 160 lb
5. Race:

Adverse Event/PRODUCT INFORMATION

1. Check all that apply:
   - Product Use Error
   - Product Use Error with Different Manufacturer of Same Medicine
   - Adverse Event

2. Substance Associated in Adverse Event
   - Common (q.v. xxxxxxxx)
   - Disability or Permanent Damage
   - Life-threatening
   - Congenital Anomaly/Defect
   - Hospitalization - initial or protracted
   - Other Serious (Important Medical Events)
   - Required Information as Prevent Permanent Impairment/Damage (Diagnosis)

3. Date of Event (mm/dd/yyyy):
   - 5/25/2010
4. Date of本案 (mm/dd/yyyy):
   - 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 Test and Laboratory Data, Including Diagnoses
   - Chest X-ray (5/19/2010), Positive for Pneumonia

7. Other Relevant Information, Including Procedures
   - Light smoker (cig pack a week)

SUSPECT MEDICAL DEVICES

1. Brand Name
   - Blu Cigs
2. Common Device Name
   - e-cigarette
3. Manufacturer Name, City and State
   - Blu Cigs, Unknown (www.blu-cigs.com)
4. Model
   - Starter Kit
5. Lot #
6. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other
7. If implanted, Give Date (mm/dd/yyyy)
8. If Explanted, Give Date (mm/dd/yyyy)
9. Is this a Single Use Device that was Reprocessed and Reused on a Patient?
   - Yes ☐ No ☑
10. If Yes to Item No. 9, Enter Name and Address of Reprocesser

CONCURRENT MEDICAL PRODUCTS

Product names and therapy data (include treatment of event)

RECEIVED
JUN 01 2010
MEDWATCH GTH

Note: This form must be signed by the reporting person. Use of this form does not constitute an admission that medical personnel or the product caused or contributed to the event.
 electronic cigarette purchased from e-smoke.net was advertised as "not having ANY carcinogens" and "all cartridges from rev.96 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 tracers in it and malfunctioned. This can be a serious health threat to the people seeking benefits from this product. FDA needs to investigate ASAP.

RECEIVED
MAY 20 2010
MEDWATCH CTU

DSS
MAY 20 2010

FORM FDA 2500 (8/96) Submission of a report does not constitute an admission that medical personnel or product caused or contributed to the event.

Compliance
Individual Safety Report

OLUNTARY reporting of adverse drug or device experiences

I bought a item from Innovative Smoking to stop smoking and paid 220.33 for the item and 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 bouht and the managtry 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 small 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 afford

MEDWATCH

MEDWATCH CTU

Submitted by: [Redacted]

MEDWATCH

Date: 04/13/2011

Page: 04/10

FORM FDA 3500 (M/18) Submisson of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
Before I purchased the product, I felt that it was safe for consumption. However, after using it, I started experiencing nausea and vomiting. I suspect that there might be a problem with the product.

I am writing to report this adverse event. I have been using the product for several months, and I have not experienced any issues before. However, in the past week, I started feeling unwell after consuming the product. I have consulted with my doctor, and they advised me to stop using the product immediately. I have also contacted the manufacturer to inform them of the issue.

I am attaching a copy of my medical records for your reference. I hope that this information will be helpful in your investigation. Thank you for your time and consideration.

Sincerely,

[Name]

Date: [Current Date]

Mall to: MEDWATCH
1-800-FDA-0178

Fax to: 1-800-FDA-0178

[Optional: Additional comments or questions]

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
The FDA Safety Information and Adverse Event Reporting Program

1. Product Identifier
   a. Product Identifier: Blu E-cigarettes

2. Date of Events
   a. Date of Events: 03/01/2010

3. Date of Report
   a. Date of this Report: 03/03/2010

4. Other Relevant History, Including Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, medication problems, etc.)
   a. Other Relevant History: After 3 days of using Blu brand electronic cigarettes I experienced what I may only guess to be my first migraine in my life. Above my left eye I had a pounding pain and an extreme sensitivity to light and sound. Effects went away when I stopped smoking the cigarette but came right back when I tried to smoke it again later. Since stopping the product I have experienced none of these affects. Why is something not even tasted allowed to be sold in the USA?

5. Reaction to Use
   a. Reaction:
      - Dose or Amount: ______________
      - Frequency: ______________
      - Route: ______________

6. Dosage of Drug (unknown, give duration/Route for unknown)
   a. Dosage: ______________
   b. Route: ______________
   c. Duration: ______________

7. Event Abbreviated or Described in Additional Information
   a. Event: ______________

8. Additional Information
   a. Yes: ______________
   b. No: ______________

9. Other Information
   a. Received: MAR 4 2010
   b. MEDWATCH CTU: MAR 4 2010

10. Other Information
    a. Yes: ______________
    b. No: ______________

11. Event Followed After Use
    a. Stopped or Decreased? ______________
    b. Yes: ______________
    c. No: ______________

12. Event Reexperienced After Withdrawal
    a. Yes: ______________
    b. No: ______________

13. Other Information
    a. Yes: ______________
    b. No: ______________

14. Other Information
    a. Yes: ______________
    b. No: ______________

15. Other Information
    a. Yes: ______________
    b. No: ______________

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.
I bought an electronic cigarette and want to report a very bad adverse effect. Your ban of them. As a pack a day smoker for 25 years, I thought there was no hope. I tried all the NRTs that the market had to offer, even non-conventional ones. Hypnosis, voodoo doctor black 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

I smoked over 2 packs a day. Now down to 0 packs.
has been monitoring me for an unrelated health issue. Found my lung CAT scans clearer and my blood test results much better than 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 ulterior 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
Product: Green Smoke, Inc.
Device: Electronic cigarette

Adverse Event:
- Severe headache and nausea

Other Relevant History:
- 20 years smoking history

Form FDA 2500 (809)
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
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 occurred after continued use of the smoking everywhere electronic cigarettes. I would say, 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 "e-cigarette" industry have a

RECEIVED
JUL 29 2009
MEDWATCH CTU

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that material contained or the product caused or contributed to the event.
much higher accountability for both product testing and quality control.
B. Other relevant history including pre-existing medical conditions, condition of the patient, or so of use of the smoking elsewhere "e-cigarettes"
A PATIENT HISTORY
1. Patient Identifier (b) (6)
   a. Name
   b. Date of Birth
   c. Sex
   d. Weight

2. ADVERSE EVENT (Attach Additional Sheet if Necessary)
   a. Onset of Event
   b. Date of Onset
   c. Description of Event

3. Cause of Event
   a. Event Type
   b. Event Location

4. Related Treatment/Laboratory Data, Including Date

RECEIVED
JAN 28 2011
MEDWATCH CTU

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

PRODUCT ANALYSIS
Product Available for Evaluation? (Do not send product to FDA)
   a. Yes
   b. No
   c. Returned to manufacturer

FORM FDA 3500 (B/45)
Submission of a report does not constitute an admission that medical personnel of the product caused or contributed to the event.
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-ciggs are 100% natural and there is nothing that can hurt you. I'm 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
The FDA Safety Information and Adverse Event Reporting Program

1. Patient Identification
   a. Name: [Redacted]
   b. Age at Time of Event: 19
   c. Sex: Male
   d. Weight: 185 lbs

2. Nature of Event
   a. Date of Event: 12/13/09
   b. Type of Event: Death
   c. Diagnosis or Reason for Use: Smoking cessation

3. Event Source
   a. Source of Information: OTC

4. Type of Event
   a. Injury or Other Event: Death
   b. Cause of Death: Smoking cessation

5. Submitting Organization
   a. Name: OTC
   b. Address: [Redacted]

6. Relevant Tests/Laboratory Data, Including Date
   a. N/A

7. History of smoking for 13 years.

8. Product Availability
   a. Product Available for Evaluation: Yes
   b. If Yes, Product Addendum: [Redacted]

9. Other Comments/Information
   a. [Redacted]

FORM 3500 (6/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
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

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

I am a 2 pack a day cigarette smoker and that is why I used the product.
The warning clearly states do not use if atomizer is not functioning properly due to risk 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.
DSS
SEP 03 2009
Patient quit smoking a 15 pack/yr habit in July of 2009 and started using a Joyetech 510 brand electronic cigarette and various flavors of 16mg/ml "aliquid" 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 "halo" around light objects. Patient was diagnosed with the early stages of Posterior Subcapsular Cataract 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

**RECEIVED**

SEP 17 2010

**MEDWATCH CTU**
seen by ophthalmologist (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 patient's life during the time frame of aggressive cataract development was the switch from smoking to the use of electronic cigarette product.

DSS
SEP 17 2010
Patient Information:
- Age: 74
- Date of Birth: 12/24/63
- Gender: Female
- Weight: 122 lbs
- Height: 55.5 lbs

Check all that apply:
- [ ] Adverse Event
- [X] Product Use Error
- [ ] Problem with Different Manufacturer of Same Medicine
- [ ] Other

Check all that apply:
- [ ] Death
- [ ] Disability or permanent damage
- [ ] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [ ] Hospitalization: initial or prolonged
- [ ] Other Serious/Important Medical Events
- [ ] Required intervention to Prevent/Improve/Manage/ pavement

Date of Event:
- Initial: 11/06/2010
- Date of this Report: 12/19/2010

Details of Event, Problem or Product Use Error:
- Age 74 discharged from hospital on 11/14/2010 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 discharge pulmonologist gave the OK to use electronic cigarette instead of smoking 3 packs on expensive nicotine patches. (b) smoked 40 years. Got the $Joy 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

5. Relevant Tests/Laboratory Data, Including Dates:

RECEIVED
DEC 30 2010
MEDWATCH CTU

Product Available for Evaluation?
- [ ] Yes
- [ ] No

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

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

3. Occupation:

4. Also Reported to:
- [ ] Manufacturer
- [ ] User Facility
minute" wife and daughter asked him if he was in pain, etc. while the wife called 911. Once on the
time 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 us
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 Prescribing Medical Conditions (e.g., allergies, react, pregnancy, smoking and alcohol use, hypertension/dysfunction, etc.) (continued)

Heart attack 1997, 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.

P. Concomitant Medical Products and Therapy Dates (exclude treatment of event) (continued)

DSS
DEC 30 2010
I used an electronic cigarette for the first time. Took 30 mg at 11 a.m. 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, woke 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 better like myself again. I am wondering if it was the e-cig. that made me feel this way.
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-cigarette community, you are condemning me and others like myself to continued tobacco use. But that's most likely your goal. My personal health has been GREATLY IMPROVED by the use of these devices. Again, you all should be ashamed!
**Individual Safety Alert**

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

**CC / MPI:**
- pt states sx started soon after using electronic cigarette

He presented with cough. It is located in the lung. It is described as constant and worsening 8 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, Q6-8 PRN, for a total of 5 oz and *** PRN cough/congestion ***
- Amoxicillin 500 mg Cap, 1 Capsule(s), PO, Q8HR, 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.
- Eyes/Nose/Throat: The patient denied epigastric pain 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 98.9°F tympanic
- respiration rate is 16 breaths per minute quiet
- SBP is 97% room air
- RR is 80 bpm radial regular
- blood pressure at Left Arm while Sitting is 120/70 mmHg

**JUL 28 2009**

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

**DSS**

**JUL 28 2009**

(UC) - C - URGENT CARE
(486.0) - 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, Q8-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:
(98203) 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, rest/fluids

DSS
JUL 28 2009

Electronic cigarette purchased from o2smoke.net was advertised as "not having any carcinogens" and "all cartridges from non-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 malfunctioned. This can be a serious health threat to the people seeking benefits from this product. FDA needs to investigate ASAP.

RECEIVED
MAY 20 2010
MEDWATCH CTU
quality control over the e-liquids. I'm just opposed to such a strong statement based on such little real evidence.
I bought the e-cigarette 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 started having a very high white blood count that no one can find a reason for. Also since stopping the use of the product I have had a continued cough. I fear these are all problems caused by the product.

RECEIVED
JUL 27 2009
MEDWATCH CTU

I have been having numerous blood tests over the past 9 months with white counts as high as 13,000.

DSS
JUL 28 2009

Smoking, have developed a serve fatty liver and diabetes is very hard to control now. For reasons unknown.

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.
I have been using electronic cigarettes for about two months 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 issue an outright ban of a great former tobacco smoker. Now totally tobacco free.
product that can help millions of Americans stop smoking, or continue to "vape" in a safe way.
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 got 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.

I smoked at least 1 pack of cigarettes a day for 13 years, and now I'm free!
No adverse reaction. Am using this e-juice to change my diet 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 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 cig...something even Chantix couldn't accomplish. Actually, I'm not opposed to the FDA wanting to exert some control.

RECEIVED
JUL 9 2009
MEDWATCH CTU
quality control over the e-liquids. I'm just opposed to such a strong statement based on such little real evidence.
RECEIVED
MAR 19 2010
MEDWATCH CTU
DSS
MAR 19 2010

PRODUCTS AFFECTED
Products Available for Examination? (Do not return product to FDA)

FORM FDA 3500 (8/96) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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-liquid 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 non-smokers and sensitive non-smokers 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.

DSS
MAR 19 2010
Individual Safety Report

MED WATCH

UNITARY reporting of
net, product problems and
product use errors

DOCS

age of

CDER

44.134

A. PATIENT INFORMATION

1. Patient Identifier
   (b) (6)

2. Age at Time of Event
   (b) (6)

3. Sex
   Female
   Male

4. Weight
   175 lbs

B. ADVERSE EVENT PRODUCT PROBLEM OR ERROR

1. Check that apply:
   O Adverse Event
   O Product Problem (e.g., defect/misfunction)
   O Product Use Error

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   O Death
   O Disability or Permanent Damage
   O Life-threatening
   O Congenital Anomaly/Defect
   O Hospitalization - Initial or prolonged
   O Other Serious (Impairment Medical Event)
   O Required intervention to Prevent Permanent Impairment/Damage (Device)

3. Date of Event

4. Data of this Report

E. SUSPECT PRODUCT(S)

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

2. Date or Amount

3. Details of Use (If unknown, give best estimate for best estimate)
   9, 10

4. Diagnosis or Reason for Use (Indication)
   TREAT - SCRE

5. Lot #

6. Expiration Date

F. SUSPECT MEDICAL DEVICE

1. Brand Name
   EZ BUFFER

2. Common Device Name
   EZ BUFFER

3. Manufacturer Name, City and State
   800 STEELE ST. CANADA

4. Model #

5. Lot #

6. Operator of Device
   Healthcare Professional
   User Facility
   Other

G. REPORTER

1. Name and Address

H. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
   Yes
   No

I. Was Returned to Manufacturer?

J. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (include treatment of event)

K. REPORTER (see confidentiality section in back)

1. Name and Address

Phone:

L. MEDWATCH CTU

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JAN 2 2011

7 Other Relevant History, including Presuming Medical Condition(s) (e.g., allergies, nausea, pregnancy, smoking and alcohol use, concomitant problems, etc.)

8. If a single-use device, was the device reprocessed and reused on a patient?

Yes

No

9. If Yes to item 10, Enter Name and Address of Reprocessor

10. Other Relevant History, Including Presence of Medical Condition(s) (e.g., allergies, nausea, pregnancy, smoking and alcohol use, concomitant problems, etc.)

11. If Yes to item 10, Enter Name and Address of Reprocessor

12. Health Professional? Yes
    13. Occupation
    Retired

14. Age Reported To:
    Manufacturer
    User Facility
    Other
I WANT TO REPORT Adverse EFFECTS of my 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 A HEART ATTACK I SAID NEVER. HE THEN MADE ME DO A STRESS TEST, CAME OUT OK. RECENTLY HAD BLOOD TESTS. THE MORTALITY RATE FOR ALL TIMES INTO THE DOCTOR MY SLOWING HEART RATE WAS AT 40 BEATS A MINUTE ALL THREE TIMES. SINCE I STARTING REALL CIGS AGAIN MY HEART BEAT IS BACK TO 65 PER MINUTE. I CAN ONLY CONCLUDE THAT THE 2 CIG ARTIFICIALLY REDUCED MY HEART RATE. ALSO WONDER IF IT COULD HAVE
CONTRIBUTED TO BELL'S 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 ROYAL MANUFACTURERS BECAUSE I COULDN'T FIND NO ADVERSE EFFECTS ON LINE MAY CONTACT ME AT 3016345687(b). THANK YOU HOSPITALIZATION WAS FOR THE BELL'S PALSY.

DSS
AUG 16 2010
After using an 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.

DSS
JUL 21 2010
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 diagnosed with pleurisy and fluid in lungs. The e-cigarette uses water vapor.
B7. Other relevant history, including preexisting medical conditions continued

using e-cigarette.
I read an article online 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 get a month's 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 e-cig 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.

8. 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.
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 ups 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)
For VOLUNTARY reporting of adverse events, product problems and product use errors

Internet Submission - Page 1

U.S. Department of Health and Human Services

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

MedWatch
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier
2. Age at Time of Event, or Date of Birth:
   (b)(6)
3. Sex
   □ Female
   □ Male
4. Weight
   (b)(6) lb
   or (b)(6) 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)
   (b)(6)
4. Date of this Report (mm/dd/yyyy)
   (b)(6)

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 juice 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.

RECEIVED
MAR 9 2011
MEDWATCH CTU

6. Relevant Tests/Laboratory Data, Including Dates
   -last chest x-ray was 3-4 months ago which
   show spot in left lung which has been there

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, smoking, alcohol use, heart/kidney problems, etc.)
   Diagnosed with emphysema back in 1996

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)
   X-Cigarette
   (b)(6)
   HCig - on battery

2. Dose or Amount
   Frequency
   Route

3. Dates of Use (if unknown, give duration to the best estimate)
   #1 09/01/2009   03/21/2011
   #2

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

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

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

E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other

6. Catalog #
5. Expiration Date (mm/dd/yyyy)
7. If Implanted, Give Date (mm/dd/yyyy)
8. If Implanted, Give Date (mm/dd/yyyy)

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

10. 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)

G. REPORTER (See confidentiality section on back)
1. Name and Address
2. Phone #
   (b)(6)
3. E-mail
4. Also Reported to:
   □ Manufacturer
   □ User Facility
   □ Distributor/Importer

Form Approved: OMB No. 0910-0991. Expires: 10/31/08
See OMB statement on reverse.

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.
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.
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 I'm already seeing problems with my health. I'm 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 I'm not sure how to explain the reason I'm getting them but I never really had problems with
nose bleeds in my past I havr had about 5 since I have started using the e cigarette just 1 WEEK ago!
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.

RECEIVED
JUN 28 2011
MEDWATCH CTU
GreenSmoke and e-cigarette company uses propylene glycol as 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.

RECEIVED
AUG 03 2011
MEDIWATCH CTU
CDER

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

Internet Submission - Page 1

**A. PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>1. Patient Identifier</th>
<th>2. Age at Time of Event, or Date of Birth</th>
<th>3. Sex</th>
<th>4. Weight</th>
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<tbody>
<tr>
<td>(b) (b)</td>
<td>(b) (b)</td>
<td>Female</td>
<td>18 lb</td>
</tr>
</tbody>
</table>

**B. ADVERSE EVENT PRODUCT PROBLEM OR HIGH**

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 (Device)

3. Date of Event (mm/dd/yyyy): 08/11/2011
4. Date of this Report (mm/dd/yyyy): 09/27/2011

**C. PRODUCT AVAILABILITY**

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

- [ ] Yes
- [ ] No
- [ ] Returned to Manufacturer:

**D. SUSPECT PRODUCT**

1. Name, Strength, Manufacturer (from product label)
   - [ ] cigarette 1
   - [ ]

2. Dose or Amount

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

4. Diagnosis/Reason for Use (Indication)

5. Event Aborted After Use
   - [ ] Yes
   - [ ] No

6. Event Repeated After Reintroduction?

7. Lot #

8. Expiration Date

9. NDC or Unique ID

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Lot #
6. Operator of Device
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] Other
7. Catalog #
8. Expiration Date (mm/dd/yyyy)
9. Serial #
10. Other #

**F. OTHER CONCOMITANT MEDICAL PRODUCTS**

Product names and therapy dates (exclude treatment of event)

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

<table>
<thead>
<tr>
<th>1. Name and Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (b)</td>
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<table>
<thead>
<tr>
<th>2. Health Professional?</th>
</tr>
</thead>
</table>
| [ ] Yes
| [ ] No

<table>
<thead>
<tr>
<th>3. Occupation</th>
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<td>Pharmacist</td>
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<th>4. Also Reported to</th>
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<td>[ ] Manufacturer</td>
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<tr>
<td>[ ] User Facility</td>
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<tr>
<td>[ ] Distributor/Importer</td>
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**RECEIVED SEP 28 2011**

MEDWATCH CTU

7. Other Relevant History, including Presenting Medical Conditions (e.g., allergies, rash, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
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.
## MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems:

Internet Submission - Page 6

### FDA Comments:

<table>
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<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>Dose</th>
<th>Unit</th>
<th>Route</th>
<th>Frequency Interval</th>
<th>Unit</th>
<th>Is Concomitant</th>
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### Diagnosis for Use

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FRA Comments:

- whanpj: [*******] 2011-09-28-08.02.26 [*******]
- USDHHS/VOLUNTARY/193395_17189_20110927.xml
- Route To: AERS : Electronic
- Route To: DQRS : Paper
- Route To: Misc. : Paper
- Send copy to Center or Tobacco Products

Mail to: MEDWATCH or FAX to:

9800 Fishers Lane
Rockville, MD 20852-0787
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.
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.
<table>
<thead>
<tr>
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**FDA Comments:**

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Wilson: ******** 2011-10-18-08.46.25 ********
USPFDAWVOLUNTARY_194500_8181_20111017.xml
Route To: AERS : Electronic
Route To: DQRS : Paper
Route To: CDRH : Paper
I need a copy for Tobacco Center
```
I was using an electronic cigarette when I started having chest pain and an extremely rapid heartbeat. I called an ambulance and was transported to the hospital. The cigarette brand was N-Joy.

RECEIVED
JAN 23 2012
MEDWATCH CTU
RECEIVED
JAN 20 2012
MEDWATCH CTU

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.
B5. Describe event or problem continued

ith both Propylene Glycol and Vegetable Glycerin. I tried to use their most popular flavor, which was Atomic Cinnadice 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 Cinnadice 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.
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Internet Submission - Page 1

A. PATIENT INFORMATION
1. Event Identification
   - Event Method:
     - (b) (6)
   - Age at Time of Event, or Date of Birth:
     - 40 Yrs
   - Sex:
     - Female
   - Weight:
     - 155 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. Adverse Event
   - Event Type:
     - Include External Events
     - Include Internal Events
   - Description:
     - E-Cigarettes. Shortness of breath and extreme bloating.

C. PRODUCT AVAILABILITY
   - Product Available for Evaluation?
     - Yes
     - Returned to Manufacturer on

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   - E-liquid 32mg KOV

E. SUSPECT MEDICAL DEVICE
1. Brand Name
   - Vape
2. Generic Drug Name
   - Vape
3. Manufacturer Name, City and State
   - Rijo Ranch, New Mexico

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
2. Health Professional?
   - Yes
   - Other Health Professional
3. Occupation
4. Also Reported To:
   - Manufacturer
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.
**MEDWATCH**

The FDA Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1

**A. PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>1. Patient Identifier Unspecified</th>
<th>2. Age at Time of Event, or Date of Birth</th>
<th>3. Sex</th>
<th>4. Weight</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>35 Years</td>
<td>Female</td>
<td>135 lb</td>
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</table>

**B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR**

Check all that apply:

1. Adverse Event
2. Product Problem (e.g., defects/instructions)
3. Product Use Error with Different Manufacturer of Same Medicine

Outcome(s) Attributed to Adverse Event (Check all that apply):

- Death: 01/25/2012
- Disability or Permanent Damage (mm/dd/yyyy)
- Life-threatening
- Congenital Anomaly/Birth Defect
- Hospitalization: Initial or prolonged
- Other Serious (Important Medical Events)
- Required intervention to Prevent Permanent Impairment/Damage (Devices)

Date of Event (mm/dd/yyyy): 02/11/2012

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; while a liquid nicotine and propylene glycol. Although he will not disclose the specific ratio of nicotine to propylene glycol, he knows that the process involving which the building and filling of cartridges is likely tainted with (b)(4) My understanding is that the mixture contained in the flavor cartridges (b)(6) sells in the US contains... 

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

(b)(6) customers have been reporting a series of side effects derived from the use of (b)(6) 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.

**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)(6) products 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)**

<table>
<thead>
<tr>
<th>1. Name, Strength, Manufacturer (from product label)</th>
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<tr>
<td>(b)(6)</td>
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</table>

**2. Dose or Amount**

Dose: 1 mg to 18 mg
Frequency: Daily
Route: Oral

**3. Dates of Use (if unknown, give duration) (b)(4)**

<table>
<thead>
<tr>
<th>Start Date</th>
<th>End Date</th>
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<td>01/25/2012</td>
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</table>

| (b)(6) |

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

- Smoking Cessation

**5. Event Altered After Use Stopped or Dose Reduced?**

- Yes
- No

| (b)(6) |

**6. Lot #**

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**7. Expiration Date**

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**8. Suspect Medical Device**

**9. NDC # or Unique ID**

- N/A

**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

Product names and/or dosage levels, including treatment of event (b)(4) Electronic Cigarettes, Smoking Cessation Aid - As claim (Cont...)

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

- (b)(6)

**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

A mixture of propylene glycol, liquid nicotine and other flavorings. However (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 employees, 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 KNOWLINGLY 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 choking 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 complaints regarding our products and the side effects they are experiencing. While it may not be clear at this point what the long term effect of (b)(4) will be on consumers, it most certainly will become evident within a few years. And the kidney 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 consumer products. Again, this was stated by (b)(6) whom oversees the design, manufacturing and production of (b) products.
(b)(6) has expressed 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 experienced 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, stomach unrest, diarrhea, shortness of breath and palpitations. Customers
have been reporting a series of side effects derived fro
F. Other (Concomitant) medical products

d in the (b)(6) website. Clear and obvious non-compliance not to advertise as a smoking cessation product.
<table>
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<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>Dose</th>
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<th>Route</th>
<th>Frequency Dosage Interval Unit</th>
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**FDA Comments:**

WALKERC: ********* | 2012-02-13 11:01:34 | *********  
USFDAMIVOLUNTARY_201229_13950_20120211.xml  
Route To: CDRF  
: Paper

Mail to: MEDWATCH  
or FAX to:  
5600 Fishers Lane  
1-800-FDA-0178  
Rockville, MD 20852-0787  
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
For VOLUNTARY reporting of adverse events, product problems and product use errors

Internet Submission - Page 1

A. PATIENT INFORMATION

Patient Identifier: (b)(6)

2. Age at Time of Event, or Date of Birth: 35 Year

3. Sex

☑ Female ☐ Male

4. Weight

145 lb

R. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

☑ Adverse Event ☑ Product Problem (e.g., defects/malfunctions)

☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event

☐ Death: (mm/dd/yyyy) ☐ Disability or Permanent Damage

☐ Life-Threatening ☐ Congenital Anomaly/Birth Defect

☐ Hospitalization - Initial or protracted ☐ Other Serious (Important Medical Events)

☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

Date of Event: (mm/dd/yyyy) 02/25/2012

4. Date of this Report (mm/dd/yyyy) 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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

☐ E-Cigarette Strawberry-High Green Smart Living

D. 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 #

S801 & S808

5. Operator of Device

Health Professional

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

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

F. OTHER CONCURRENT 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)

2. Phone #

3. Health Professional?

☐ Yes ☐ No

4. Also Reported To:

☐ Consumer/Other non Health Professional

☐ Manufacturer

☐ 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.
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.
### Drug Reaction Information

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<th>Drug</th>
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### FDA Comments:

MILSONJ: [******] 2012 02 27 10:00:31 [******]
USFDAMMVOLUNTARY_202088_14727_20120226.xml
Route To: AERS: Electronic
Route To: DQRS: Paper
Route To: CDRH: Paper
Need Copy for CTP

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