On March 15, 2013 I started using the vapor e cigarette. After a few weeks of using the e cigarette I ended up in the hospital ER on (b)(6) and another time before that for ear congestion and hearing loss. From the time I started using the e cigarette till now I lost my hearing in my left ear with a high pitch noise that never goes away. Before I started using the ear cigarette I never had any problems with my ears. My ENT doctor believes I will never have my hearing back in my left ear.

CTU

JUN 27 2013

- Relevant Tests/Laboratory Data, Including Dates

I have had two hearing test done one on (b)(6) & (b)(6) and a MRI (b)(6) also blood work. I have further testing with a specialist in (b)(6) in the next week or so. I have been on several medications and steroids which have not helped.
For VOLUNTARY reporting of adverse events, product problems and product use errors

A. PATIENT INFORMATION

1. Patient Identifier
   (b) [In confidence]

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

3. Sex
   □ Female
   □ Male

4. Weight
   185 lbs

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):
   07/10/2013

4. Date of this Report (mm/dd/yyyy):
   07/10/2013

5. Describe Event, Problem or Product Use Error

When coworker uses electronic cigarette, I get a burning sensation in my lungs and irritation in my eyes.

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

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

2. Dose or Amount
   Frequency
   Route
   #1
   #2

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

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

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

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name
   UNKNOWN

2. Common Device Name
   Electronic Cigarette

3. Manufacturer Name, City and State
   UNKNOWN

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

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

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

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

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

E. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
   (b) (6)

2. Health Professional?
   □ Yes
   □ No

3. Occupation
   □ Yes
   □ No

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

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
B7. Other relevant history, including preexisting medical conditions continued
cigarettes.
Section A - About the Problem

What kind of problem was it? (Check all that apply)
- X Were hurt or had a bad side effect (including new or worsening symptoms)
- □ Used a product incorrectly which could have or led to a problem
- □ Noticed a problem with the quality of the product
- □ Had problems after switching from one product maker to another maker

Did any of the following happen? (Check all that apply)
- X Hospitalization - admitted or stayed longer
- □ Required help to prevent permanent harm (for medical devices only)
- □ Disability or health problem
- □ Birth defect
- □ Life-threatening
- □ Death (Include date):
- □ Other serious/important medical incident (Please describe below)

Date the problem occurred (month/day/year):
4/13

Tell us what happened and how it happened. (Include as many details as possible)

IN APRIL, I HAD BEEN USING CIG AND E-CIG. WHEN I WAS AROUND MY GRANDDAUGHTER. SHE TOOK A HIT AND KNEW I WAS AROUND. SHE THOUGHT IT MIGHT BE CLEAR.

List any relevant tests or laboratory data if you know them. (Include dates)

For a problem with a product, including
- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

Go to Section B

For a problem with a medical device, including
- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

Go to Section C (Skip Section B)
HAD A MINI STROKE, DIDN'T TELL ANYONE. ON (b) (6) HAD BEEN USING REG CIG + ECIG. I'M STARTING TO GET VERY AGITATED, MY MIND WAS GOING 100 MPH AND I COULDN'T EVEN WRITE OR SIGN MY NAME SO I WENT TO THE ER. AFTER 3 DAYS I WAS DIAGNOSED WITH NICOTINE OVERLOAD. SO THEY COST ME $2,000 TO FIND OUT.
**Section B – About the Products**

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)

SAVEASMOKER

Name of the company that makes the product

SAVEASMOKER

<table>
<thead>
<tr>
<th>Expiration date (mm/dd/yyyy)</th>
<th>Lot number</th>
<th>NDC number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Strength (for example, 250 mg per 500 mL or 1 g)

18 mg, E LIQUID

Quantity (for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)

SMOKE LIKE A CIGARETTE

Frequency (for example, twice daily or at bedtime)

ALL DAY

How was it taken or used (for example, by mouth, by injection, or on the skin)?

INHALED

Date the person first started taking or using the product (mm/dd/yyyy): 3/27/13 to 3/31/13 (b)(6)

Date the person stopped taking or using the product (mm/dd/yyyy):

Why was the person using the product (such as, what condition was it supposed to treat)?

WAS USING IT TO GET AWAY FROM TAR & OTHER THING IN CIG.

BUT STILL GET NICOTINE

Did the problem stop after the person reduced the dose or stopped taking or using the product?

☐ Yes ☐ No

Did the problem return if the person started taking or using the product again?

☐ Yes ☐ No ☐ Didn’t restart

Do you still have the product in case we need to evaluate it? (Do not send the product to FDA. We will contact you directly if we need it.)

☐ Yes ☐ No

[Go to Section D (Skip Section C)]

**Section C – About the Medical Device**

Name of medical device

Name of the company that makes the medical device

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Was someone operating the medical device when the problem occurred?

☐ Yes ☐ No

If yes, who was using it?

☐ The person who had the problem
☐ A health professional (such as a doctor, nurse, or aide)
☐ Someone else (Please explain who)

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in (mm/dd/yyyy)

Date the implant was taken out (if relevant) (mm/dd/yyyy)

[Go to Section D]

For more information, visit http://www.fda.gov/MedWatch

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
Section D – About the Person Who Had the Problem

Person's Initials: (b) (6)
Sex: ☒ Male
Age (at time the problem occurred) or Birth Date: 66
Weight (Specify lbs or kg): 175
Race: W

List known medical conditions (such as diabetes, high blood pressure, cancer, heart disease, or others)

NONE

Please list all allergies (such as to drugs, foods, pollen, or others).

CODINE

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

SMOKER

List all current prescription medications and medical devices being used.

PYLOSPEC

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

CENTRUM SILVER, LOW DOSE ASPIRIN

Section E – About the Person Filling Out This Form

We will contact you only if we need additional information. Your name will not be given out to the public.

Last name: (b) (6)
First name: (b) (8)
Number/Street: (b) (8)
City and State/Province: (b) (6)
Country: (b) (6)
ZIP or Postal code: (b) (6)
Telephone number: (b) (6)
Email address: (b) (6)
Today's date (mm/dd/yyyy): 07/22/2013

Did you report this problem to the company that makes the product (the manufacturer)? ☐ Yes ☒ No

May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product? ☐ Yes ☒ No

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA.

Mail or fax the form to:

Mail:
MedWatch
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Fax:
1-800-332-0178 (toll-free)

Thank you for helping us protect the public health.

For more information, visit http://www.fda.gov/MedWatch
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
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: 30 Years
3. Sex [ ] Female [ ] Male
4. Weight 100 lb

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

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

3. Date of Event (mm/dd/yyyy) 08/07/2013
4. Date of this Report (mm/dd/yyyy) 08/07/2013

5. Describe Event, Problem or Product Use Error
After smoking a disposable EonSmoke electronic cigarette regularly for about a week, I developed a horrible, tubercular-sounding cough. I woke up in the middle of the night with coughing fits multiple times. I had no other cold symptoms whatsoever, and nothing else about my behavior had changed, so I am fairly certain it was the product.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
Race: White, Medical Conditions: n/a Allergies: n/a
Important Information: drinks regularly RX Meds: none
OTC Meds: n/a

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

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   #1 Name: EonSmoke Electronic Cigarette
   Strength:
   Manufacturer: EonSmoke LLC

2. Name:
   Strength:
   Manufacturer:

2. Dose or Amount
   #1
   Frequency
   Route
   Inhalation

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

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

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

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

7. Lot #
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

4. Model #
5. Operator of Device
   [ ] Health Professional
   [ ] Lay User/Patient
   [ ] Other:

   Catalog #
   Expiration Date (mm/dd/yyyy)

   Serial #
   Other #

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

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

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

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

G. REPORTER (See confidentiality section on back)
1. Name and Address
   Name: (b) (6)
   Address:
   City:
   State: --
   ZIP:
   Phone #
   E-mail:

2. Health Professional?
   [ ] Yes [ ] No

3. Occupation
   (b) (6)

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: [ ]
**MEDWATCH**

The FDA Safety Information and Adverse Event Reporting Program

**A. PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>1. Patient Identifier (b) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Age at Time of Event or Date of Birth:</td>
</tr>
<tr>
<td>44 Years</td>
</tr>
<tr>
<td>3. Sex</td>
</tr>
<tr>
<td>☑ Female</td>
</tr>
<tr>
<td>4. Weight</td>
</tr>
<tr>
<td>250 lb</td>
</tr>
</tbody>
</table>

In confidence

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

Check all that apply:

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

**2. Outcomes Attributed to Adverse Event**

<table>
<thead>
<tr>
<th>(Check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Death: (mm/dd/yyyy)</td>
</tr>
<tr>
<td>☑ Disability or Permanent Damage</td>
</tr>
<tr>
<td>☑ Life-threatening</td>
</tr>
<tr>
<td>☑ Congenital Anomaly/Birth Defect</td>
</tr>
<tr>
<td>☑ Hospitalization - initial or prolonged</td>
</tr>
<tr>
<td>☑ Other Serious (Important Medical Events)</td>
</tr>
<tr>
<td>☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)</td>
</tr>
</tbody>
</table>

**3. Date of Event (mm/dd/yyyy) (b) (6) | 4. Date of this Report (mm/dd/yyyy) 08/09/2013**

**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>
</tr>
</thead>
<tbody>
<tr>
<td>#1 Name: E-cigs</td>
</tr>
<tr>
<td>Strength:</td>
</tr>
<tr>
<td>Manufacturer:</td>
</tr>
</tbody>
</table>

| 2. Name: |
| Strength: |
| Manufacturer: |

**E. SUSPECT MEDICAL DEVICE**

<table>
<thead>
<tr>
<th>1. Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Common Device Name</td>
</tr>
<tr>
<td>3. Manufacturer Name, City and State</td>
</tr>
</tbody>
</table>

| 4. Model # |
| 5. Operator of Device |
| Catalog # |
| Expired Date (mm/dd/yyyy) |
| ☑ Lay User/Patient |
| ☑ Other: |
| Serial # |

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

Product names and therapy dates (exclude treatment of event)

<table>
<thead>
<tr>
<th>1. Name and Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name (b) (6)</td>
</tr>
<tr>
<td>Address (b) (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Health Professional?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Yes  ☑ No</td>
</tr>
<tr>
<td>3. Occupation</td>
</tr>
<tr>
<td>4. Also Reported to:</td>
</tr>
<tr>
<td>☑ Manufacturer</td>
</tr>
<tr>
<td>☑ User Facility</td>
</tr>
<tr>
<td>☑ Distributor/Importer</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>1. Name and Address (See confidentiality section on back)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name (b) (6)</td>
</tr>
<tr>
<td>Address (b) (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Health Professional?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Yes  ☑ No</td>
</tr>
<tr>
<td>3. Occupation</td>
</tr>
<tr>
<td>4. Also Reported to:</td>
</tr>
<tr>
<td>☑ Manufacturer</td>
</tr>
<tr>
<td>☑ User Facility</td>
</tr>
<tr>
<td>☑ Distributor/Importer</td>
</tr>
</tbody>
</table>

**PLEASE TYPE OR USE BLACK INK**

**FORM FDA 3500 (1/09)**

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

<table>
<thead>
<tr>
<th>Patient Identifier</th>
<th>Age at Time of Event or Date of Birth</th>
<th></th>
<th>Sex</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24 Years</td>
<td></td>
<td>Female</td>
<td>139 lb</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**
- 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):** 09/19/2013

**Date of this Report (mm/dd/yyyy):** 09/19/2013

### 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):**
   - Honey eGo-CES
     - Manufacturer: Goosalma
   - Eliquid Refill Menthol Flavor
     - Strength: 24mg
     - Manufacturer: MAYA Electric Smoke

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

- Name and Address
- Phone 
- E-mail
- City:  
- State:  
- ZIP:

**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.
**MEDWATCH**

The FDA Safety Information and Adverse Event Reporting Program

---

**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>(b)</td>
<td>(b) (6)</td>
<td>Female</td>
<td>115 lb</td>
</tr>
</tbody>
</table>

---

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

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

**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)

**C. Dose or Amount**

<table>
<thead>
<tr>
<th>1.</th>
<th>2.</th>
<th>3.</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**D. EVENT AT TIME OF USE**

- [x] Yes
- [ ] No
- [ ] Doesn't Apply

- [ ] Yes
- [ ] No
- [ ] Doesn't Apply

**E. SUSPECT MEDICAL DEVICE**

1. **Brand Name**
   - Torando eGo-C Slim

2. **Common Device Name**
   - Torando eGo-C Slim

3. **Manufacturer Name, City and State**
   - JACVAPOUR

4. **Model #**
5. **Lot #**

6. **Catalog #**

7. **Expiration Date**

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

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

10. **Operator of Device**

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

Product names and therapy dates (exclude treatment of event)

---

**G. REPORTER**

(See confidentiality section on back)

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

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

3. **Occupation**

4. **Also Reported to**
   - [ ] Manufacturer
   - [ ] User Facility
   - [ ] Distributor/Importer

---

**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.
**MEDWATCH**

The FDA Safety Information and Adverse Event Reporting Program

### A. PATIENT INFORMATION

1. **Patient Identifier**
   - **ID:** (b) (6)

2. **Age at Time of Event or Date of Birth:**
   - 45 Years (b) (6)

3. **Sex:**
   - Male

4. **Weight:**
   - 235 lbs

### 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**
4. **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event**
   - Death: (mm/dd/yyyy)
   - Disability or Permanent Damage: (mm/dd/yyyy)
   - Life-threatening: (mm/dd/yyyy)
   - Critical Illness or Hospitalization: (mm/dd/yyyy)
   - Other Serious (Important Medical Events): (mm/dd/yyyy)
   - Other: (mm/dd/yyyy)

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

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

5. **Describe Event, Problem or Product Use Error**
   - Was smoking Blu e cig for several months when just a few weeks ago had the feeling of passing out. Heart rate was slow to the point of blocking out. Went to ER was released and had to wear a holter monitor. They caught several events from fast erratic beats sometimes my heart was adding beats that were out of rhythm and others were slow were I skipped a beat or 2. I stopped using the product and it's been 2 weeks no more issues. I am wearing an event monitor now to double check but I have not noticed any symptoms like I had since stopping using product. So not only did I have the...
B.5. Describe Event or Problem (continued)

... feeling of passing out and feeling as if I was dying (seriously) I am now out $1700 and counting for my ER and doctor visits I still have the product in my possession I would love for someone to analyze what is in this product. I was going to the gym walking 3 miles on treadmill, lifting etc... that all stopped once the event occurred. been worried of having a heart attack. I was having heart palpitations every day until roughly 10 hrs after stopping use of product. the I felt like a rush of energy hit me and started to feel better.

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)
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: 64 Years
   (b) (6)
3. Sex
   Female
4. Weight
   190 lb
   or ___ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. [] Adverse Event
2. [X] Product Problem (e.g., defects, malfunctions)
3. [X] Product Use Error
4. [ ] Problem with Different Manufacturer of Same Medicine

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

3. Date of Event (mm/dd/yyyy)
   08/31/2013
4. Date of this Report (mm/dd/yyyy)
   09/03/2013

5. Describe Event, Problem or Product Use Error
   Kissing my partner who was using an e-cigarette caused me to get “pigmented contact cheilitis” which is very painful.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.):
   Race: White
   Medical Conditions: Allergies: Chemical sensitivities - formaldehyde
   Second-hand smoke causes sinus infections, restrictive airways, migraines. Important Information: RX Meds: OTC Meds:

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

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   #1 Name: E-Cigarette
   Strength:
   Manufacturer:

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. 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)

G. REPORTER (See confidentiality section on back)
1. Name and Address
   Name: _____________________________
   Address: _____________________________
   City: _____________________________
   State: (b) (6) __________
   ZIP: _____________________________
   Phone #: _____________________________
   E-mail: _____________________________

2. Health Professional? [ ] Yes [ ] No
3. Occupation

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

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

A. PATIENT INFORMATION
1. Patient Identifier
(b) [Confidential]
2. Age at Time of Event or Date of Birth:
45 Years
(b) (6)
3. Sex
☑ Male
☐ Female
4. Weight
190 lb
☐ or kg

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

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

3. Date of Event (mm/dd/yyyy)
09/04/2013
4. Date of this Report (mm/dd/yyyy)
09/05/2013

5. Describe Event, Problem or Product Use Error
I get constant headaches at work from various e-cigs, smokers indoors. I have to move frequently 2-3 times a day to get away from various e-cig smokers. I have repeatedly asked Human Resources to help over a year and a half, have not received any assistance or policy change.

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

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
#1 Name: e-cig
Strength: unknown
Manufacturer: unknown
#2 Name:
Strength:
Manufacturer:

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.
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors
Page 1 of 2

A. PATIENT INFORMATION
1. Patient Identifier:
(b) (5)
2. Age at Time of Event or Date of Birth:
67 Years
3. Sex:
☑ Female
☐ Male
4. Weight:
190 lbs

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

3. Date of Event (mm/dd/yyyy)
07/15/2013
4. Date of this Report (mm/dd/yyyy)
09/12/2013

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

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name
e-cig
2. Common Device Name
e-cig
3. Manufacturer Name, City and State
e-cig

4. Model #
Lot #
5. Operator of Device
☐ Health Professional
☐ Lay User/Patient
☐ Other

Catalog #
Expiration Date (mm/dd/yyyy)

Serial #
Other #

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

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

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

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

G. REPORTER (See confidentiality section on back)
1. Name and Address
Name: (b) (6)
Address: (b) (6)
City: (b) (6)
State (b)
ZIP (b)
Phone #: (b) (6)
E-mail: (b) (6)

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

5. If you DO NOT want your identity disclosed to the manufacturer, place an “X” in this box: ☐
B.5. Describe Event or Problem (continued)

... e-cig and had a heart attack, would they have paid my bill? They should be required to post the same information in the store that is on-line. I shudder to think of the problems down the road!

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)
**MEDWATCH**

The FDA Safety Information and Adverse Event Reporting Program

### A. PATIENT INFORMATION

1. **Patient Identifier**
   - [ ] Age at time of Event or Date of Birth: 42 Years
   - [ ] Sex: Female
   - [ ] Weight: 150 lb

2. **Dose or Amount**

<table>
<thead>
<tr>
<th>#1</th>
<th>Frequency</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>#1</th>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/01/2012</td>
<td>09/20/2013</td>
<td></td>
</tr>
</tbody>
</table>

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

   #1 another attempt to quit smoking

5. **Lot #**

<table>
<thead>
<tr>
<th>#1</th>
<th>#2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. **Expiration Date**

<table>
<thead>
<tr>
<th>#1</th>
<th>#2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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)
4. [ ] 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 prolonged
   - [ ] Other Serious (Important Medical Events)
   - [ ] Required Intervention to Prevent Permanent Impairment/ Damage (Device(s))

3. **Date of Event (mm/dd/yyyy)**
   - 09/21/2013

### C. PRODUCT AVAILABILITY

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

[ ] Yes
[ ] No

**Returned to Manufacturer on:** (mm/dd/yyyy)

### D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer (from product label)**
   - [ ] Name: e-cigarettes
   - [ ] Strength: Manufacturer.

2. **Name:**
   - [ ] Strength: Manufacturer.

### F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

1. **Name and Address**
   - Name: [ ]
   - Address:

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

3. **Occupation**

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

**Please Type or Use Black Ink**

**Form Approved: OMB No. 0910-0291, Expires: 12/31/2011**

**See CMS statement on reverse.**

**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

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)
   Age at time of Event or Date of Birth: 3 Years (b) (6)
   Sex: Male
   Weight: 20 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

1. Check all that apply:
   - Adverse Event
   - Product Problem (e.g., defects/malfunctions)
   - Product Use Error

2. 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)

3. Date of Event (mm/dd/yyyy) (b) (6)
   Date of this Report (mm/dd/yyyy) 09/24/2013

4. Describe Event, Problem or Product Use Error
   This 3 year old male was restrained in a car seat. In the rear seat of his mother's vehicle. While she was driving the e-cigarette she was charging, in the factory charge, suffered a catastrophic failure and the e-cigarette expelled the copper coils out of the tube. The superheated copper coils ricocheted off of the ceiling of the car and into the patient's car seat, setting his trousers on fire. The fire was subsequently extinguished. The patient suffered burns to his left elbow, left flank, and left buttocks.

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)
   - Name: White Rhino E-Cigarette
   - Strength:
   - Manufacturer:

2. Name:
   - Strength:
   - Manufacturer:

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name
   e-cigarette

3. Manufacturer Name, City and State
   Name: White Rhino
   City: State: -- Zip:

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
   Name: (b) (6)
   Address: (b) (6)
   City: (b) (6)
   State: [b] ZIP: (b)
   Phone #: (b) (6)
   E-mail: (b) (6)

2. Health Professional?
   - Yes
   - No

3. Occupation
   - Other Health Professional

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

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

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.
### Section B - About the Products

**Name of the product as it appears on the box, bottle, or package (Include as many names as you see):**

![Product Name](image)

**Name of the company that makes the product:**

![Company Name](image)

- **Expiration date (mm/dd/yyyy):**
  - [None]

- **Lot number:**
  - [None]

- **NDC number:**
  - [None]

- **Strength (for example, 250 mg per 500 mL or 1 g):**
  - 18 mg

- **Quantity (for example, 2 pills, 2 puffs, or 1 teaspoon, etc.):**
  - 600 PUFFS

- **Frequency (for example, twice daily or at bedtime):**
  - NO LIMIT

- **How was it taken or used (for example, by mouth, by injection, or on the skin):**
  - BY MOUTH

- **Date the person first started taking or using the product (mm/dd/yyyy):**
  - 07/09/2012

- **Date the person stopped taking or using the product (mm/dd/yyyy):**
  - 05/29/2013

- **Why was the person using the product (such as, what condition was it supposed to treat):**
  - TO STOP SMOKING

- **Did the problem stop after the person reduced the dose or stopped taking or using the product?**
  - [Yes] [No] [ ]

- **Did the problem return if the person started taking or using the product again?**
  - [Yes] [ ] [ ] [No]

  - [ ] Didn't restart

- **Do you still have the product in case we need to evaluate it? (Do not send the product to FDA. We will contact you directly if we need it):**
  - [ ] Yes [ ] No

### Section C - About the Medical Device

- **Name of medical device:**
  - [Blank]

- **Name of the company that makes the medical device:**
  - [Blank]

- **Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them):**
  - [Blank]

- **Was someone operating the medical device when the problem occurred?**
  - [ ] Yes [ ] No

- **If yes, who was using it?**
  - [ ] The person who had the problem
  - [ ] A health professional (such as a doctor, nurse, or aide)
  - [ ] Someone else (Please explain who)

- **For implanted medical devices ONLY (such as pacemakers, breast implants, etc.):**
  - **Date the implant was put in (mm/dd/yyyy):**
    - [Blank]
  - **Date the implant was taken out (if relevant) (mm/dd/yyyy):**
    - [Blank]
**Section D - About the Person Who Had the Problem**

<table>
<thead>
<tr>
<th>Person's Initials</th>
<th>Sex</th>
<th>Age (at time the problem occurred) or Birth Date</th>
<th>Weight (Specify lbs or kg)</th>
<th>Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td></td>
<td>48</td>
<td>185</td>
<td>White</td>
</tr>
</tbody>
</table>

List known medical conditions (such as diabetes, high blood pressure, cancer, heart disease, or others)

**COPD**

Please list all allergies (such as to drugs, foods, pollen, or others).

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

**Section E - About the Person Filling Out This Form**

We will contact you only if we need additional information. Your name will not be given out to the public.

<table>
<thead>
<tr>
<th>Last name</th>
<th>First name</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>(b) (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number/Street</th>
<th>City and State/Province</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>(b) (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>ZIP or Postal code</th>
<th>Today's date (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.A.</td>
<td></td>
<td>10-3-2013</td>
</tr>
</tbody>
</table>

Telephone number

Email address

<table>
<thead>
<tr>
<th>Did you report this problem to the company that makes the product (the manufacturer)?</th>
<th>May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA.

Mail or fax the form to:

<table>
<thead>
<tr>
<th>Mail: MedWatch</th>
<th>Fax: 1-800-332-0178 (toll-free)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food and Drug Administration</td>
<td></td>
</tr>
<tr>
<td>5600 Fishers Lane</td>
<td></td>
</tr>
<tr>
<td>Rockville, MD 20857</td>
<td></td>
</tr>
</tbody>
</table>

Thank you for helping us protect the public health.

For more information, visit [http://www.fda.gov/medwatch](http://www.fda.gov/medwatch)