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U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

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

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) in confidence	(b) (6) 27 Years	☑ Female ☐ Male	165 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
(b) (6)	06/26/2013

5. Describe Event, Problem or Product Use Error

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.

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JUN 27 2013

More

6. 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.

More

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

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Vapor e cigarette 30mg
#2

2.	Dose or Amount	Frequency	Route
#1	26 mg	All day	
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 03/15/2013 -- 05/13/2013	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 03/15/2013 -- 05/13/2013	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*	8. Event Reappeared After Reintroduction?
#1 To stop smoking tobacco	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name: E cig
2. Common Device Name:
3. Manufacturer Name, City and State: Naples vapor, Cape Coral Florida

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

1. Name and Address
(b) (6)

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

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

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

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

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

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

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

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

5. Describe Event, Problem or Product Use Error

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

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

I am a non-smoker and no one in my household smokes. My employeer bars the use of cigarettes in the facility, but does not bar the use of electronic

More

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

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

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

6. Lot #
   #1
   #2

7. Expiration Date
   #1
   #2

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

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

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

Phone #

E-mail: (b) (6)

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

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

B7. Other relevant history, including preexisting medical conditions continued

cigarettes.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0291
Expiration Date: 6/30/2015
(See PRA Statement on preceding general information page)

MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

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 *(mm/dd/yyyy)*
4/1/13 AND (b) (6)

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. GOT UP APRIL 1ST AND KEPT DROPPING THING AND HAD BLURED VISION. THOUGHT IT MIGHT B

Continuation Page

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

Continuation Page

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)

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.

Continued Entries

CONTINUED ENTRY FOR: Tell us what happened and how it happened. *(Include as many details as possible)*

HAVING A MINI STROKE, DIDN'T TELL ANYONE. ON (b) (6) HAD BEEN USING REG CIG. & ECIG. IN STARTING TO GET VERY AGITATED, MY MIND WAS GOING A 1,000 MPH AND I COULDN'T EVEN WRITE OR SIGN MY NAME SO I WENT TO THE ER. AFTER 3 DAYS AND MANY TEST I WAS DIAGNOSED AS NICOTINE OVER LOAD. SO THEY COST ME $2,000. TO FIND OUT.

Back to Form

CONTINUED ENTRY FOR: List any relevant tests or laboratory data if you know them. *(Include dates)*

Back to Form

CONTINUED ENTRY FOR: List all current prescription medications and medical devices being used.

Back to Form

CONTINUED ENTRY FOR: List all over-the-counter medications and any vitamins, minerals, and herbal remedies being used.

Back to Form

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)*

SAVE A SMOKER

Name of the company that makes the product

SAVE A SMOKER

Expiration date *(mm/dd/yyyy)*	Lot number	NDC number

Strength *(for example, 250 mg per 500 mL or 1 g)*	Quantity *(for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)*	Frequency *(for example, twice daily or at bedtime)*	How was it taken or used *(for example, by mouth, by injection, or on the skin)*?
18 MG. E LIQUID	SMOKE LIKE A CIGARETTE	ALL DAY	INHALED

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

Date the person stopped taking or using the product *(mm/dd/yyyy)*: (b) (6)

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***

Section D – About the Person Who Had the Problem

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

PRYLOSEC

Continuation Page

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

CENTRUM SILVER LOW DOSE ASPRIN

Continuation Page

Go to Section E

Section E – About the Person Filling Out This Form

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

Last name	First name
(b) (6)	(b) (6)

Number/Street	City and State/Province
(b) (6)	(b) (6)

Country	ZIP or Postal code
(b) (6)	(b) (6)

Telephone number	Email address	Today's date *(mm/dd/yyyy)*
(b) (6)	(b) (6)	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:	**Fax:**
MedWatch Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	1-800-332-0178 (toll-free)

Thank you for helping us protect the public health.

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

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Consumer Report

U.S. Department of Health and Human Services

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CTP

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

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	30 Years (b) (6)	☑ Female ☐ Male	100 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

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	Frequency	Route
#1	Once daily	Inhalation
#2		

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

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

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

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

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

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

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

City: State: -- ZIP:

Phone #	E-mail
	(b) (6)

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

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

PLEASE TYPE OR USE BLACK INK

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Consumer Report

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

CTP

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

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	44 Years (b) (6)	☑ Female ☐ Male	250 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

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

I am not sure but after smoking e-cigs for about 6 months I ended up with blood clots in my lungs. They could not find a reason for then still calling them unprovoked. I just wanted it to be out there in case others share the same fate. Maybe there is a correlation between e-cigs and blood clots????

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

Unprovoked blood clots. EKG's, echo-cardiograms, numerous blood tests, artery scans, lung scans, now I am on blood thinners for an undetermined amount of time because they were unprovoked. They said I could have died.

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: Just some depression until this happened. Allergies: Sulfa products Important Information: Used to smoke RX Meds: Prozac, Seroquel, now on coumadin 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-cigs
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

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

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 03/01/2012 - 08/22/2012
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 Thought they would be safer than smoking.
#2

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

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

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

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

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

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

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

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

PLEASE TYPE OR USE BLACK INK

Consumer Report

U.S. Department of Health and Human Services

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Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
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FDA USE ONLY

Triage unit
sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (c) In confidence	24 Years	☐ Female ☑ Male	139 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/19/2013	08/19/2013

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

Started using an e-cigarette, noticed very quickly that it did have an adverse effect on my lung capacity. The device itself (manufactured by G1) was faulty and leaked the fluid very easily causing direct exposure to my lips and tounge. The fluid that was used was produced by MAYA Electronic Smoke and is the 24mg nicotine menthol flavored e-liquid in a 15ml container.

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

NA

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

Race:White Medical Conditions: Allergies: 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: Honey eGo-CE5
Strength: NA
Manufacturer: Gaosimai

#2 Name: ELiquid Refill Menthol Flavor
Strength: 24mg
Manufacturer: MAYA Electric Smoke

2. Dose or Amount	Frequency	Route
#1	--	--
#2 15ml	--	--

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

#1 08/17/2013 - 08/19/2013
#2 08/16/2013 - 08/19/2013

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

#1 smoking alternative
#2 smoking alternative

6. Lot #	7. Expiration Date
#1	#1
#2 Sku: LMT13	#2

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

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

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**
e-cigarette

2. **Common Device Name**
e-cigarette

3. **Manufacturer Name, City and State**
G1

4. Model #	Lot #	5. Operator of Device
Honey eGo-CE5		☐ Health Professional
Catalog # Gaosimai	**Expiration Date** *(mm/dd/yyyy)*	☑ Lay User/Patient
		☐ Other:
Serial #	**Other #**	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. **Name and Address**
Name: Fake Name
Address:
City: State: -- ZIP:

Phone #	E-mail

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

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

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FDA USE ONLY

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) In confidence	25 Years (b) (6)	☑ Female ☐ Male	115 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
(b) (6)	08/23/2013

5. Describe Event, Problem or Product Use Error

One week after using Torando eGo-C Cigarettes chest heavyness and pain occurred. 3-days after this started an emergency room visit was made where I was kept overnight. I was released in the morining with a diagnosis of pneumonia. I was sent home for rest and given anti-biotics

6. Relevant Tests/Laboratory Data, Including Dates

Chest x-ray, blood tests.

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

Race:White Medical Conditions: None Allergies: None Important Information: None RX Meds: None OTC Meds: Daily Vitamin

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1		
#2		

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

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

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Torando eGo-C Slim

2. Common Device Name
Torando eGo-C Slim

3. Manufacturer Name, City and State
JACVAPOUR

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

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

Phone #	E-mail
	(b) (6)

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

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

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FDA USE ONLY

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) In confidence	46 Years (b) (6)	☐ Female ☑ Male	235 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
(b) (6)	08/26/2013

5. Describe Event, Problem or Product Use Error

was smoking Blu e cigs for several months when just a few weeks ago (b) (6) had the feeling of passing out. heart rate was slow to the point of blacking 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 its 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 ...

6. Relevant Tests/Laboratory Data, Including Dates

holter monitor showed erratic beats(48 hr worn) sometimes adding or missing beats blood pressure is good. thyroid good. cholesterol good. psa good. non diabetic.

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

Race:White Medical Conditions: NONE Allergies: amoxicillen .. pollen Important Information: was quitting smoking. rare alcohol use RX Meds: NONE OTC Meds: multi vitamin

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: BLU
Strength: high
Manufacturer: BLU

#2 Name:
Strength:
Manufacturer:

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

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 01/05/2013 - 08/12/2013
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 used it to ween off of cigarettes
#2

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

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

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

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

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

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

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

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)*

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FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	64 Years (b) (6)	☑ Female ☐ Male	190 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/31/2013	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 sensitivites--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:

#2 Name:
Strength:
Manufacturer:

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

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

#1
#2

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

#1
#2

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

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

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

8. **Event Reappeared After Reintroduction?**

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

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. **Name and Address**

Name: (b) (6)
Address: (b) (6)

City: (b) (6) State: (b) ZIP:

Phone #	E-mail
	(b) (6)

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

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

PLEASE TYPE OR USE BLACK INK

U.S. Department of Health and Human Services

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FDA USE ONLY

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) In confidence	45 Years (b) (6)	☐ Female ☑ Male	190 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

5. Describe Event, Problem or Product Use Error

I get constant headaches at work from various e-cigs smokes 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, but have not received any assistance or policy change.

6. Relevant Tests/Laboratory Data, Including Dates

several doctor visits related to nausea

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

Race:White Medical Conditions: none Allergies: mountain cedar Important Information: none RX Meds: none 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-cig
Strength: unknow
Manufacturer: unkown

#2 Name:
Strength:
Manufacturer:

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

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

#1 04/04/2011 - 09/05/2013
#2

5. Event Abated After Use Stopped or Dose Reduced?

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

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

#1 not a user; i get 2nd hand smoke from e-cigs smokers
#2

8. Event Reappeared After Reintroduction?

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

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 uknown	#1 09/04/2013	unkown
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. Name and Address

Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b) ZIP: (b)

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

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

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

U.S. Department of Health and Human Services

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FDA USE ONLY

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) In confidence	67 Years (b) (6)	☑ Female ☐ Male	190 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

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

5. Describe Event, Problem or Product Use Error

In an attempt to quit smoking I got the e-cigs. After the third use, I noticed a definite increase in blood pressure and a very sick feeling. I felt as though I was about to have congestive heart failure. Since the e-cigs were the only thing new, I immediately got on-line. I found on their own web site a notice that if you had diabetes, heart problems or were pregnant you were not to use. What about the poor young women who are attempting to quit smoking because they are pregnant? What problems are going to be discovered in a few years? If I had not known my body so well, continued to use the ...

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: diabetes, high blood presure Allergies: milk Important Information: smoking RX Meds: Plavix, Furosemide, Glimepiride, Diltiazem, Qunipril, Metformin OTC Meds: 81 mg. asprin

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1		
#2		

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

#1
#2

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

#1
#2

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

5. Event Abated After Use Stopped or Dose Reduced?

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

8. Event Reappeared After Reintroduction?

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
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
Catalog #	Expiration Date *(mm/dd/yyyy)*	☑ Lay User/Patient
		☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. Name and Address

Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b ZIP: (b)

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

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

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

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 roadl

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)*

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FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	42 Years (b) (6)	☑ Female ☐ Male	150 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
(b) (6)	09/21/2013

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

throat hoarseness, raspy voice. Increased amount of mucus and phleghm. Headaches.

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: none Allergies: none Important Information: smoked 20 years RX Meds: none OTC Meds: none

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

(1)

#1 Name: e-cigarettes
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

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

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 11/01/2012 - 09/20/2013
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 another attempt to quit smoking
#2

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

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

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

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

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

Phone #	E-mail

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

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

PLEASE TYPE OR USE BLACK INK

U.S. Department of Health and Human Services

Health Care Professional CTP

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

1 / 1 Page ~~1 of 2~~

FDA USE ONLY

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

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

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
(b) (6)	09/24/2013

5. Describe Event, Problem or Product Use Error

This 3 year old male was restrained in a car seat, in the rear seat of his mothers 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 richocheted off of the ceiling of the car and into the patients 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.

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: White Rhino E-Cigarette
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

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

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

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

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

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

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

9. NDC # or Unique ID

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

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

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

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

, --, US

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

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

CTP

1/2

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)*

Clean Cig™ Regular 18mg

Name of the company that makes the product

Clean Cig™

Expiration date *(mm/dd/yyyy)*	Lot number	NDC number
NONE		

Strength *(for example, 250 mg per 500 mL or 1 g)*	Quantity *(for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)*	Frequency *(for example, twice daily or at bedtime)*	How was it taken or used *(for example, by mouth, by injection, or on the skin)*?
18mg	600 PUFFS	NO LIMIT	BY MOUTH

Date the person first started taking or using the product *(mm/dd/yyyy)*: 02/09/2013

Date the person stopped taking or using the product *(mm/dd/yyyy)*: 05/25/2013

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

TO STOP SMOKEING

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

Section D – About the Person Who Had the Problem

Person's Initials	Sex	Age *(at time the problem occurred)* or Birth Date	Weight *(Specify lbs or kg)*	Race
(b) (6)	☐ Female ☒ Male	48	185	WHITE [redacted]

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.

Continuation Page

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

Continuation Page

Go to Section E

Section E – About the Person Filling Out This Form

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

Last name	First name
(b) (6)	(b) (6)

Number/Street	City and State/Province
(b) (6)	(b) (6)

Country	ZIP or Postal code
U.S.A	(b) (6)

Telephone number	Email address	Today's date *(mm/dd/yyyy)*
(b) (6)	(b) (6)	10-3-2013

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