

# **Report Profile**

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-01-10 16:27:56

FDA ICSR ID (b) (6)

Report Key for Followup (b) (6)

# **Report Identifying Information**

Create a name to help you find this report in the future (max length: 50 characters) (b) (6)

(b) (6) exposure to e-cigarette vapor

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting? Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

Confirm Email (b) (6)

First Name (b)

Last Name (b)

Phone (b) (6)

Email (b) (6)

Country United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b)

State (b) (6)

ZIP/Postal Code (b)

Check here if you wish to remain anonymous. <blank>

May the FDA contact you to follow-up if necessary?

Preferred method of contact Email

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product?

Please describe your relationship to the person who experienced the health problem

## **Product Information**

Brand Name or Product Name <blank>

Universal Product Code (UPC) from label <br/>
<br/>
blank>

Did the product come from another country? <blank>

Product Type Other

When did the person purchase this product? <blank>

Does the person still have the product? Unknown

Description of other tobacco product type e-cigarette

Do you know where the product was purchased?

Do you know who manufactured this product? No

#### **Product Purchase Location**

#### **Manufacturer Information**

#### **Product Use Details**

When did the person open the package and start using the product that may have caused <blank>

the health problem?

When did the person stop using the product <blank> that may have caused the health problem?

How long has the person been using this <blank>

Select Unit of Measure <blank>

Was the product being used when the health Yes problem occurred?

Did the person use this product before without a problem?

Unknown

Did the person change the product in any way before using it (for example: removing a filter from a cigarette)?

Unknown

Is the affected person currently using other No tobacco products (within past month)?

Does the person who had the adverse event

also drink alcohol?

Has the affected person used other tobacco products in the past?

Please describe anything else you think the

<blank> FDA should know about this health problem

On average, number of pieces, pinches, dips, <blank> or rubs used

Please select <blank>

## **Reaction and Product Relatedness**

How soon after the product was last used did <blank> the health problem occur?

Select Unit of Measure <blank>

Did the person stop using the product when <blank> he/she had the health problem?

#### **Problem Summary**

Health problem start date 12/12/2013

Health problem end date 12/12/2013

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time hour(s)

I was attending a talk in a college auditorium. I became headachy and nauseated. I could also

Please describe the health problem or product problem:

smell something that smelled like tobacco which made me think I may be sitting next to a smoker (not actively smoking). After a few minutes I noticed that a man about two to three rows directly ahead of me (he was on the front row) was using an e-cigarette, quite openly and freely. The headache and nausea lasted until the talk was over and he left. I stayed for a book signing after that and my headache and nausea got better once the man was gone from the auditorium.

Do any of these apply to the health problem? (Select one or more)

None of the above

Outcome to date Recovered/Resolved

Was the person taken to an emergency facility? No

Was the person evaluated by a healthcare professional?

Has the person had a similar health problem or

product problem?

Please describe the similar health problem or product problem

I am sensitive to strong smells (perfumes and lotions, for example) and chemical exposures which usually make me cough. This current exposure to e-cigarette vapor wasn't close enough to make me cough, but I felt that the headache and nausea was directly linked to the vapor

problems? (select up to 5)

What are the main symptoms or health Pain, numbness, itching or unusual sensation, Tired, weak, dizzy, confused, feel bad/sick, Other problem not listed

### Affected Person

Gender Female

Pregnant No

Race (Select one or more) White

Ethnicity <blank>

Birth date of the person who experienced the health problem (b) (6)

Age of the person when the health problem

occurred

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

(6)(6)

## **Product Components**

**Other Products Used** 

**Other Tobacco Products Currently Used** 

Other Tobacco Products Used in the Past



# **Medications, Vitamins and Supplements**

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

Prevacid Solutab calcium, magnesium, Vit D baby aspirin

## **Attached Files**

None



## **Report Profile**

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-01-12\_06:48:57

FDA ICSR ID (b) (6)

Report Key for Followup

(b) (6)

# Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

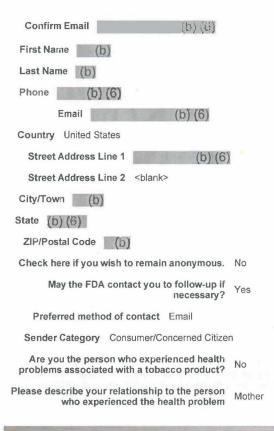
(b) (6)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)



## **Product Information**

Brand Name or Product Name unknown

Universal Product Code (UPC) from label <black>

Did the product come from another country? <black>

Product Type Other

When did the person purchase this product? <black>

Does the person still have the product? Unknown

Description of other tobacco product type Electronic cigarette

Do you know where the product was purchased? No

Do you know who manufactured this product? No

## **Product Purchase Location**

## **Manufacturer Information**

#### **Product Use Details**

When did the person open the package and start using the product that may have caused <blank> the health problem? When did the person stop using the product <blank> that may have caused the health problem? How long has the person been using this <blank> brand? Select Unit of Measure <blank> Was the product being used when the health No problem occurred? Did the person use this product before without No a problem? Did the person change the product in any way before using it (for example: removing a filter from a cigarette)? Is the affected person currently using other tobacco products (within past month)? Does the person who had the adverse event also drink alcohol?

FDA should know about this health problem

Has the affected person used other tobacco

products in the past?

Please describe anything else you think the Electronic cigarettes need to be regulated like normal tobacco products. The effects of second

On average, number of pieces, pinches, dips, or rubs used

hand exposure are unknown and potentially dangerous to the public, especially children.

Please select <blank>

## Reaction and Product Relatedness

How soon after the product was last used did <blank> the health problem occur?

Select Unit of Measure <blank>

Did the person stop using the product when <blank> he/she had the health problem?

## **Problem Summary**

Health problem start date 10/24/2013

Health problem end date 10/24/2013

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time hour(s)

Please describe the health problem or product My daughter suffered trouble breathing and aggravation to a chest cold that had all but cleared

problem: up after accidental and unintentional exposure to e-cig vapors in a restaurant.

Do any of these apply to the health problem?

(Select one or more)

Outcome to date Recovered/Resolved

Was the person taken to an emergency facility? No

Was the person evaluated by a healthcare

professional?

Has the person had a similar health problem or

product problem?

Please describe the similar health problem or product problem

<blank>

None of the above

What are the main symptoms or health problems? (select up to 5)

<u>Lungs or Breathing problem</u> (<i>such as: cough, asthma, wheezing, lung infection</i>)

#### **Affected Person**

Gender Female

Pregnant No

Race (Select one or more) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the health problem

(b) (6)

Age of the person when the health problem

occurred

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

## **Product Components**

Other Products Used

Other Tobacco Products Currently Used

Other Tobacco Products Used in the Past

Medications, Vitamins and Supplements

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

<blank>

# **Attached Files**

None



# Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-01-16\_14:05:09

FDA ICSR ID (6) (6)

Report Key for Followup

(b) (6)

# Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

(b) (6)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

Confirm Email (b) (6	
First Name (b)	
Last Name (b) (6)	
Phone (b) (6)	
Email (b) (6	)
Country United States	
Street Address Line 1 (b) (6)	
Street Address Line 2 <blank></blank>	
City/Town (b)	
State (b)	
ZIP/Postal Code (b)	
Check here if you wish to remain anonymous.	<blank></blank>
May the FDA contact you to follow-up if necessary?	Yes
Preferred method of contact Email	
Sender Category Consumer/Concerned Citizer	1
Are you the person who experienced health problems associated with a tobacco product?	Yes
Please describe your relationship to the person who experienced the health problem	<blank></blank>

## **Product Information**

Brand Name or Product Name Blu electronic cigarettes

Universal Product Code (UPC) from label 8 54055 00433

Did the product come from another country? Unknown

Product Type Cigarettes

When did the person purchase this product? 01/08/2014

Does the person still have the product? Yes

Do you know where the product was purchased?

Do you know who manufactured this product? Yes

## **Product Purchase Location**

Purchase Location Name Local tobbaco store

Country United States

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Phone <blank>

How was this product purchased? in a store

Web Address <blank>

#### Manufacturer Information

Firm/Organization Name Blu ecigs / Lorillard Technologies, Inc.

Country United States

Phone 1-888-207-4588

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town Charlotte

State North Carolina

ZIP/Postal Code 28273

Web Address http://www.blucigs.com/

## **Product Use Details**

When did the person open the package and start using the product that may have caused the health problem?

01/08/2014

When did the person stop using the product that may have caused the health problem?

01/11/2014

How long has the person been using this

Select Unit of Measure less than 7 days

Was the product being used when the health problem occurred?

Did the person use this product before without a problem?

Did the person change the product in any way before using it (for example: removing a filter No from a cigarette)?

Is the affected person currently using other tobacco products (within past month)?

Does the person who had the adverse event also drink alcohol?

Has the affected person used other tobacco yes products in the past?

How many drinks per week? <5 drinks/week

On average, number smoked 1

Please select per week

#### Reaction and Product Relatedness

How soon after the product was last used did the health problem occur?

Select Unit of Measure minute(s)

Did the person stop using the product when he/she had the health problem?

Did the symptoms from the health problem go away or get better when the person stopped or reduced the amount of product used?

Did the person start using the product again? No

How long was it before the person started using the product again? <br/>

Select Unit of Measure <biank>

Did the health problem happen again after the person started using the product again?

<blank>

## **Problem Summary**

Health problem start date 01/08/2014

Health problem end date 01/11/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time day(s)

Please describe the health problem or product problem:

Every time I used the product it would give me a headache

Do any of these apply to the health problem? (Select one or more)

None of the above

Outcome to date Recovered/Resolved

Was the person taken to an emergency facility? No

Was the person evaluated by a healthcare professional?

Has the person had a similar health problem or product problem?

What are the main symptoms or health problems? (select up to 5)

Pain, numbness, itching or unusual sensation

#### **Affected Person**

Gender Male

Race (Select one or more) White	
Ethnicity Not Hispanic or Latino	
Birth date of the person who experienced the health problem (b) (6)	
Age of the person when the health problem occurred 54	
Select Unit of Age year(s)	
Please list any known pre-existing health problems for the affected person	
Product Components	
Component Type Cigarettes	
Component Purchase Location	,
Component i dichase Location	
Component Manufacturer Information	
	mullipped contract transports
Product Components	
Component Type Menthol	
Component Purchase Location	Tries Promiters Used
Component Manufacturer Information	Soort phonon Proposite Committy Uses
Product Components	Coller February Products Dang in the Pres
Component Type FSC paper	
Component Purchase Location	
Component Manufacturer Information	

Product Components	
Component Type Flavoring	THE REAL PROPERTY AND ADDRESS OF THE AMERICAN PR
Component Purchase Location	
Component Manufacturer Information	
Product Components	or legal deatherly magazines.
Component Type Other	· Production of the part of the second state o
Component Purchase Location	
Component Manufacturer Information	mining to the second
Other Products Used	finance Consideration of the Park Constitution of the Constitution
Other Tobacco Products Currently Used	MANAGE III. To 1785 AND TO TENNIN SUFFEE
Other Tobacco Products Used in the Past	eftyr mmi 5 / n. hm?
Medications, Vitamins and Supplements	
Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem	

# **Attached Files**

None



## Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-01-21000:21:55

FDA ICSR ID (b) (6)

Report Key for Followup (b) (6)

# **Report Identifying Information**

Create a name to help you find this report in the future (max length: 50 characters)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

Confirm Email (b) (6

First Name [

Last Name (b)

Phone <blank>

Email (b) (6)

Country United States

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Check here if you wish to remain anonymous. <blank>

May the FDA contact you to follow-up if Yes necessary?

Preferred method of contact Email

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product?

Please describe your relationship to the person who experienced the health problem

<blank>

#### **Product Information**

Brand Name or Product Name <blank>

Universal Product Code (UPC) from label <br/>
<br/>
blank>

Did the product come from another country? <blank>

Product Type Other

When did the person purchase this product? <blank>

Does the person still have the product? Yes

Description of other tobacco product type e-cigarettes

Do you know where the product was

purchased?

Do you know who manufactured this product? No

#### **Product Purchase Location**

### Manufacturer Information

## **Product Use Details**

When did the person open the package and start using the product that may have caused the health problem?	d <blank></blank>
When did the person stop using the product that may have caused the health problem?	
How long has the person been using this brand?	
Select Unit of Measure <blank></blank>	
Was the product being used when the health problem occurred?	
Did the person use this product before without a problem?	
Did the person change the product in any way before using it (for example: removing a filter from a cigarette)?	r No
Is the affected person currently using other tobacco products (within past month)?	
Does the person who had the adverse event also drink alcohol?	
Has the affected person used other tobacco products in the past?	
Please describe anything else you think the FDA should know about this health problem	
On average, number of pieces, pinches, dips, or rubs used	
Please select <black></black>	

## **Reaction and Product Relatedness**

How soon after the product was last used did the health problem occur?

Select Unit of Measure <br/>
bid the person stop using the product when he/she had the health problem?

Unknown

# **Problem Summary**

Health problem start date <blank>

Health problem end date <blank>

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time month(s)

neighbor smokes e-cigarettes, second hand fumes have caused painful respiratory and auditory

Please describe the health problem or product

problems, eye redness, no prior health conditions. because user can get 300-400 puffs per cartridge, the second hand smoke in a residential situation is endless and has caused tremendous distress and health problem...for family dog as well. Many trips to doctors including one trip to the emergency room for severe tightness to the chest and problem breathing.

Do any of these apply to the health problem?

(Select one or more)

Disability, Hospitalization, Treatment Received

Outcome to date Ongoing

Was the person taken to an emergency facility?

Was the person evaluated by a healthcare professional?

Date the person was first seen by a healthcare professional for this health problem

12/14/2013

received including results of any tests (such as x-rays, lab results, or blood work)

Please describe any treatment the person blood work, lab results each has traces of various chemicals and nicotine (I am not a smoker), now need inhaler and am being treated for asthma related symptons directly related to ecigarette second hand smoke.

Has the person had a similar health problem or product problem?

Please describe the similar health problem or product problem

<blank>

problems? (select up to 5)

What are the main symptoms or health Burn, <u>Allergic</u> reaction, <u>Lungs or Breathing problem</u> (<i>such as: cough, asthma, wheezing, lung infection</i>), <u>Medical test(s)</u> abnormal

### Affected Person

Gender Female

Pregnant No

Race (Select one or more) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the health problem (b) (6)

Age of the person when the health problem occurred

42

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

## **Product Components**

#### Other Products Used

### Other Tobacco Products Currently Used

#### Other Tobacco Products Used in the Past

# **Medications, Vitamins and Supplements**

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

<blank>

## **Attached Files**

None



## Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-01-21[20:13:48

FDA ICSR ID (6)

Report Key for Followup (b) (6)

# Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product

Confirm Email (b) (6)

First Name (b) (6)

Last Name (b) (6)

Phone <blank>

Email (b) (6)

Country United States

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State (b)

ZIP/Postal Code <blank>

Check here if you wish to remain anonymous. <blank>

May the FDA contact you to follow-up if necessary?

Preferred method of contact Email

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product?

Please describe your relationship to the person who experienced the health problem

<blank>

## **Product Information**

Brand Name or Product Name unknown

Universal Product Code (UPC) from label <blank>

Did the product come from another country? <blank>

Product Type Other

When did the person purchase this product? //2014

Does the person still have the product? <blank>

Description of other tobacco product type electronic cigarette nicotine vapor

Do you know where the product was

<blank> purchased?

Do you know who manufactured this product? <biank>

## **Product Purchase Location**

#### **Manufacturer Information**

#### **Product Use Details**

When did the person open the package and start using the product that may have caused <blank> the health problem?

When did the person stop using the product that may have caused the health problem?

<blank>

How long has the person been using this brand?

Select Unit of Measure less than 7 days

Was the product being used when the health problem occurred?

Did the person use this product before without No

a problem?

Did the person change the product in any way before using it (for example: removing a filter from a cigarette)?

Is the affected person currently using other No

tobacco products (within past month)? Does the person who had the adverse event

also drink alcohol?

Has the affected person used other tobacco products in the past?

Please describe anything else you think the FDA should know about this health problem

The person affected was not the user.

On average, number of pieces, pinches, dips,

<blank> or rubs used

Please select <blank>

On average, number of pieces used <blank>

Please select <blank>

On average, number of dabs used <biank>

Please select <blank>

# **Reaction and Product Relatedness**

How soon after the product was last used did 15 the health problem occur?

Select Unit of Measure minute(s)

Did the person stop using the product when Unknown he/she had the health problem?

## **Problem Summary**

Health problem start date 01/21/2014

Health problem end date 01/21/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted

Select Unit of Time day(s)

Please describe the health problem or product problem:

electronic cigarette brought into small office by co-worker. Bad taste in mouth could not get rid of with eating or rinsing. Bad smell stuck with body. Experienced nausea, stomach pain, and slight headache. Stomach pain and nausea eased with fresh air. Went home, changed, showered, brushed teeth and gargled. Irrigated sinuses with warm salt water. This releaved most of the bad taste and smell. Does this happen to anyone else? Why are these chemicals allowed to be used in public places?

Do any of these apply to the health problem? (Select one or more)

None of the above

Yes

Outcome to date Recovered/Resolved

Was the person taken to an emergency facility?

Was the person evaluated by a healthcare professional?

Has the person had a similar health problem or product problem?

Please describe the similar health problem or

It happened once before after exposure to electric cigarette.

problems? (select up to 5)

product problem

What are the main symptoms or health <u>Digestive System</u> problem (<i>such as: nausea/vomiting, stomach pain, diarrhea, constipation</i>)

## **Affected Person**

Gender Female

Pregnant No

Race (Select one or more) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the health problem

(b) (6)

Age of the person when the health problem

occurred

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

Depression, chronic occipital headaches, arthritis.

## **Product Components**

# **Other Products Used**

## Other Tobacco Products Currently Used

## Other Tobacco Products Used in the Past

# **Medications, Vitamins and Supplements**

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem design of the

## **Attached Files**

None



# **Report Profile**

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-01-31015:44:51

FDA ICSR ID (b) (6)

Report Key for Followup (b) (6)

# **Report Identifying Information**

Create a name to help you find this report in the future (max length: 50 characters)

Electronic Cigarettes (6)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

Confirm Email <blank>

First Name <blank>

Last Name <blank>

Phone <blank>

Email <blank>

Country United States

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State (b) (6)

ZIP/Postal Code <blank>

Check here if you wish to remain anonymous. Yes

May the FDA contact you to follow-up if necessary?

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product?

Please describe your relationship to the person <blank> who experienced the health problem

### **Product Information**

Brand Name or Product Name Logic, BLack label. Both Menthol and non-menthol cartridges.

Universal Product Code (UPC) from label <br/> <b

Did the product come from another country? No

Product Type NA

When did the person purchase this product? 09/20/2013

Does the person still have the product? Yes

Do you know where the product was Yes purchased?

Do you know who manufactured this product? No

## **Product Purchase Location**

Purchase Location Name 7-11

Country United States

Street Address Line 1 Multiple 7-11's across (b) (6)

Street Address Line 2 <blank>

City/Town <blank>

State (b) (6)

ZIP/Postal Code <blank>

Phone <blank>

How was this product purchased? in a store

Web Address <blank>

## **Manufacturer Information**

Firm/Organization Name <br/> <br/> <br/> <br/> dank>

Country <blank>

Phone <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Web Address <blank>

#### **Product Use Details**

When did the person open the package and start using the product that may have caused 09/20/2013

the health problem?

<blank>

When did the person stop using the product that may have caused the health problem?

How long has the person been using this brand?

Select Unit of Measure Months

Was the product being used when the health problem occurred? Yes

Did the person use this product before without a problem?

Did the person change the product in any way before using it (for example: removing a filter No from a cigarette)?

Is the affected person currently using other tobacco products (within past month)?

Does the person who had the adverse event also drink alcohol?

Has the affected person used other tobacco products in the past?

How many drinks per week? 5-6 drinks/week

Please describe anything else you think the FDA should know about this health problem

If the cause of this Cough, weaz, moisture, is the e-cigarette and it doesn't stop here and will simply accumulate as i continue to smoke, it's my opinion that the effect will feel almost like drowning. Breathing in too much water, very, very, Slowly.

## Reaction and Product Relatedness

How soon after the product was last used did <blank> the health problem occur?

Select Unit of Measure <blank>

Did the person stop using the product when No he/she had the health problem?

## **Problem Summary**

Health problem start date 12/01/2013

Health problem end date 01/31/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted 2

Select Unit of Time month(s)

I've picked up the habit of smoking E-Cigarette's lately. My Brand of choice at the moment is Logic. They work great at ridding the urge to smoke a standard cigarette. But after prolonged use, about 3 months, I've noticed that I'm starting to develop a very slight cough. This cough feels as though my lungs are now lined with too much moisture or humidity. Go into a steam room for an hour a day, every day, for months, and I guarantee you'll develop some kind of lung issue. Although I continue to smoke them, but only because the cough is not constant and is very slight. But it IS noticeable. These will absolutely need some sort of regulation and testing in order to fully know the risks. Also, If I do not smoke enough of it, I get what feels like a blood rush to Please describe the health problem or product problem: my head. My eyes will get slightly watery and a slight headache will develop. This is not something I experienced with cutting down on cigarette in the past when the E-cigarette was not present. But I can probably conclude that since the E-cigarette can be smoked anywhere, and practically all day long, I do so. This overload of nicotine may be the cause of this effect.

Do any of these apply to the health problem?

None of the above

Outcome to date Ongoing

Was the person taken to an emergency facility? No

Was the person evaluated by a healthcare No professional?

No

Has the person had a similar health problem or

product problem?

(Select one or more)

Please describe the similar health problem or

<blank> product problem

What are the main symptoms or health problems? (select up to 5)

<u>Lungs or Breathing problem</u> (<i>such as: cough, asthma, wheezing, lung infection</i>)

## Affected Person

Gender Male

Race (Select one or more) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the

(b) (6) health problem

Age of the person when the health problem 25

occurred

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

# **Product Components**

#### Other Products Used

# Other Tobacco Products Currently Used

Brand Name or Product Name Camel Menthol Silvers

**Product Type** Cigarettes

On average, number smoked 3

Please select per week

Duration of Use 6-12 months

### Other Tobacco Products Used in the Past

# Medications, Vitamins and Supplements

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

<blank>

## **Attached Files**

None



# Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-02-02 12:50:57

FDA ICSR ID (b) (6)

Report Key for Followup

(D) (D

# Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

e-cigs

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

Confirm Email (b) (6) First Name (b) Last Name (b) (6) Phone <blank> Email (b) (6) Country United States Street Address Line 1 (b) (6) Street Address Line 2 <blank> City/Town (b) (6) State (b) (6) State/Province <blank> ZIP/Postal Code (b) Check here if you wish to remain anonymous. <blank> May the FDA contact you to follow-up if necessary? Preferred method of contact Email Sender Category Consumer/Concerned Citizen Are you the person who experienced health problems associated with a tobacco product? Please describe your relationship to the person Husband who experienced the health problem

## **Product Information**

Brand Name or Product Name <br/>
Universal Product Code (UPC) from label <br/>
bid the product come from another country? <br/>
Product Type Other<br/>
When did the person purchase this product? <br/>
Does the person still have the product? Yes<br/>
Description of other tobacco product type Electronic cigarettes<br/>
Do you know where the product was purchased?<br/>
No<br/>
Do you know who manufactured this product? No

### **Product Purchase Location**

### **Manufacturer Information**

#### **Product Use Details**

When did the person open the package and start using the product that may have caused the health problem?

<blank>

When did the person stop using the product that may have caused the health problem?

<blank>

How long has the person been using this

<blank>

brand?

Select Unit of Measure <blank>

Was the product being used when the health problem occurred?

<blank>

Did the person use this product before without a problem?

<blank>

Did the person change the product in any way before using it (for example: removing a filter from a cigarette)?

<blank>

On average, number smoked <blank>

Please select <biank>

or rubs used

Please select per day

#### Reaction and Product Relatedness

How soon after the product was last used did the health problem occur?

<blank>

Select Unit of Measure <blank>

Did the person stop using the product when he/she had the health problem?

<blank>

## Problem Summary

Health problem start date 11/10/2013

Health problem end date 11/15/2013

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time month(s)

Please describe the health problem or product problem:

High milligram liquid nicotine can be purchased to be consumed through an e-cig. Information is provided by manufacturer on how to mix and produce your own preferred amount. Currently my husband's nicotine level is 36mgs. His addiction has led to constant consumption or chain vaping. Health problems include chest pains that caused a blackout, difficulty in sleeping, loss of appetite, anxiety, and loss of reality.

Do any of these apply to the health problem?

(Select one or more)

Life Threatening, Treatment Received

Outcome to date Ongoing

Was the person taken to an emergency facility?

Was the person evaluated by a healthcare professional?

Date the person was first seen by a healthcare professional for this health problem

12/10/2013

Please describe any treatment the person received including results of any tests (such as x-rays, lab results, or blood work)

Was scheduled for a stress test to evaluate heart condition, but did not follow through.

Has the person had a similar health problem or product problem?

product problem

Please describe the similar health problem or Diagnosed with Angina in 2005. No life threating symptoms until Nov. 2013. Has smoked regular cigarettes for 30+ years.

What are the main symptoms or health problems? (select up to 5) <u><u>Heart or Blood</u> problem (<i>>such as: chest pain, heart attack, high or low blood pressure, palpitations bleeding, clotting</i>/i>), <u>Mood or Mental health</u> problem (<i>>such parts of the problem (<i>>such problem (<i>>such parts of the parts of as: anxiety, agitation, depression</i>)

## **Affected Person**

Gender Male

Race (Select one or more) White

Ethnicity <blank>

Birth date of the person who experienced the health problem

(b) (6)

Age of the person when the health problem occurred

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

High cholesterol. Angina

## **Product Components**

Other Products Used

Other Tobacco Products Currently Used

Other Tobacco Products Used in the Past

Medications, Vitamins and Supplements

**Attached Files** 

None



# REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-02-06001:30:51

FDA ICSR ID (b) (6)

Report Key for Followup (b) (6)

# **Report Identifying Information**

Create a name to help you find this report in the future (max length: 50 characters)

(b) (6)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

### **Contact Information - Sender**

Confirm Email <blank>

First Name <blank>

Last Name <blank>

Phone <blank>

Email <blank>

Country United States

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State (b)

ZIP/Postal Code <blank>

Check here if you wish to remain anonymous. Yes

May the FDA contact you to follow-up if necessary?

<blank

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product?

Yes

Please describe your relationship to the person who experienced the health problem

<blank>

### **Product Information**

Brand Name or Product Name Vista Vapors

Universal Product Code (UPC) from label <blank>

Did the product come from another country? No

Product Type Other

When did the person purchase this product? 10//2013

Does the person still have the product? Yes

Description of other tobacco product type Electric Cigarette

Do you know where the product was purchased?

Do you know who manufactured this product? No

#### **Product Purchase Location**

Purchase Location Name Vista Vapors

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Phone <blank>

How was this product purchased? website mail order

Web Address http://www.vistavapors.com/

#### **Manufacturer Information**

#### **Product Use Details**

When did the person open the package and start using the product that may have caused 10//2013 the health problem?

When did the person stop using the product that may have caused the health problem?

02//2014

How long has the person been using this

Select Unit of Measure Months

Was the product being used when the health problem occurred?

Did the person use this product before without a problem?

Did the person change the product in any way

before using it (for example: removing a filter No from a cigarette)? Is the affected person currently using other

tobacco products (within past month)?

Does the person who had the adverse event No also drink alcohol?

Has the affected person used other tobacco products in the past?

Please describe anything else you think the FDA should know about this health problem

The electric cigarette gets hot when you use it and alters the taste buds. I just recently realized what was turning my taste buds black and it also yellows your teeth more than a cigarette does. It does help with nicotine cravings but I will be switching over to the nicotine patches tomorrow.

On average, number of pieces, pinches, dips, or rubs used

Please select per day

On average, number of pinches used <blank>

Please select <blank>

#### Reaction and Product Relatedness

How soon after the product was last used did the health problem occur?

Select Unit of Measure month(s)

Did the person stop using the product when he/she had the health problem?

Did the symptoms from the health problem go away or get better when the person stopped or Unknown

reduced the amount of product used?

Did the person start using the product again? No

How long was it before the person started using the product again?

Select Unit of Measure <blank>

Did the health problem happen again after the person started using the product again?

Not Applicable

## **Problem Summary**

Health problem start date <blank>

Health problem end date <blank>

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time month(s)

Please describe the health problem or product problem:

I have been using Visa Vapors electric cigarette and it turned the taste buds on my tongue black.

Do any of these apply to the health problem? (Select one or more)

<blank>

Outcome to date Unknown

Was the person taken to an emergency facility? No

Was the person evaluated by a healthcare No

professional?

Has the person had a similar health problem or product problem?

Please describe the similar health problem or

product problem

I have not gone to a doctor and will switch from the e-cigarette to nicotine patches.

What are the main symptoms or health problems? (select up to 5)

#### Affected Person

Gender Female

Pregnant <blank>

Race (Select one or more) Black or African American

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the

(b)(6)health problem

Age of the person when the health problem

occurred

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

# **Product Components**

#### Other Products Used

# **Other Tobacco Products Currently Used**

Brand Name or Product Name Nicotine patch

Product Type <blank>

Duration of Use Less than 1 month

### Other Tobacco Products Used in the Past

Brand Name or Product Name Belmont Milds

**Product Type** Cigarettes

On average, number smoked 10

Please select per day

Duration of Use More than 12 months

# Medications, Vitamins and Supplements

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

### **Attached Files**

None



# REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-02-09 18:11:42

FDA ICSR ID (b) (6)

Report Key for Followup

# Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters) (6)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

### **Contact Information - Sender**

Confirm Email (b) (6) First Name (b) Last Name (b) Phone (b) (6) Email (b) (6) Country United States Street Address Line 1 (b) (6) Street Address Line 2 <blank> City/Town (b) State (b) (6) ZIP/Postal Code (b) Check here if you wish to remain anonymous. No May the FDA contact you to follow-up if necessary? Preferred method of contact Email Sender Category Consumer/Concerned Citizen Are you the person who experienced health problems associated with a tobacco product? Please describe your relationship to the person <blank> who experienced the health problem

#### **Product Information**

Universal Product Code (UPC) from label unknown
Did the product come from another country? Unknown
Product Type Other
When did the person purchase this product? 12/10/2013
Does the person still have the product? Yes
Description of other tobacco product type e-cigarett
Do you know where the product was purchased? Yes
Do you know who manufactured this product? No

### **Product Purchase Location**

Purchase Location Name Vapor King

Country United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b)

State (b) (6)

ZIP/Postal Code unknown

Phone (b) (6)

How was this product purchased? in a store

Web Address <blank>

#### **Manufacturer Information**

#### **Product Use Details**

When did the person open the package and start using the product that may have caused 11/08/2013 the health problem?

When did the person stop using the product that may have caused the health problem? 02/08/2014

How long has the person been using this brand?

Select Unit of Measure Months

Was the product being used when the health problem occurred? Yes

Did the person use this product before without a problem?

Did the person change the product in any way before using it (for example: removing a filter No from a cigarette)?

Is the affected person currently using other tobacco products (within past month)?

Does the person who had the adverse event also drink alcohol?

Has the affected person used other tobacco products in the past?

Please describe anything else you think the FDA should know about this health problem

On average, number of pieces, pinches, dips, or rubs used

Please select per week

### **Reaction and Product Relatedness**

How soon after the product was last used did the health problem occur? 5

Select Unit of Measure minute(s)

Did the person stop using the product when he/she had the health problem?

### **Problem Summary**

Health problem start date 02/04/2014

Health problem end date 02/04/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted

Select Unit of Time hour(s)

Please describe the health problem or product problem:

Seizure (verified through MRI) resulting in a 2-day hospitalization.

Do any of these apply to the health problem?

Hospitalization (Select one or more)

Outcome to date Ongoing

Was the person taken to an emergency facility? Yes

Was the person evaluated by a healthcare professional?

Yes

Date the person was first seen by a healthcare

professional for this health problem

02/04/2014

<blank>

Please describe any treatment the person received including results of any tests (such as x-rays, lab results, or blood work)

Treated with IV fluids, blood thinners and anti-epileptic medication. MRI indicated a seizure had occurred.

Has the person had a similar health problem or

product problem?

Please describe the similar health problem or

product problem

What are the main symptoms or health

problems? (select up to 5)

Other problem not listed

#### Affected Person

Gender Female

Pregnant No

Race (Select one or more) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the

health problem

(b) (6)

Age of the person when the health problem

occurred

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

Asthma, COPD, RA

# **Product Components**

#### Other Products Used

## Other Tobacco Products Currently Used

Brand Name or Product Name Marlboro 72

Product Type Cigarettes

On average, number smoked 10

Please select per day

Duration of Use Less than 1 month

### Other Tobacco Products Used in the Past

Brand Name or Product Name Echo

Product Type Cigarettes

On average, number smoked 20

Please select per day

Duration of Use More than 12 months

# Medications, Vitamins and Supplements

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

Advair Diskus, ProAir HFA, Lexapro, Albuteral Sulfate, Aleve, Aspirin, Caltrate Calcium w/D, Clacium-magnesium-zinc, Multi Vitamin, Pótasium Gluconate, Super B Complex w Vitamin C and Folic Acid, Naproxenen and Kappra,

### **Attached Files**

None



# REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-02-18010:53:17

FDA ICSR ID (b) (6)

Report Key for Followup

(b) (6)

# Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

(b) (6) Cigarette

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

### **Contact Information - Sender**

```
Confirm Email
                               (b) (6)
First Name (b)
Last Name (b)
Phone (b) (6)
      Email
                          (b) (6)
Country United States
  Street Address Line 1
  Street Address Line 2 (b)
City/Town (b)
State (b) (6)
 ZIP/Postal Code (b)
 Check here if you wish to remain anonymous. No
       May the FDA contact you to follow-up if
                                              Yes
                                 necessary?
   Preferred method of contact Email
 Sender Category Consumer/Concerned Citizen
    Are you the person who experienced health
 problems associated with a tobacco product?
Please describe your relationship to the person who experienced the health problem
                                              <blank>
```

### **Product Information**

Brand Name or Product Name Green Smart Living

Universal Product Code (UPC) from label <br/>
blank>
Did the product come from another country? <br/>
Product Type Other

When did the person purchase this product? 02/04/2013

Does the person still have the product? Yes

Description of other tobacco product type Electronic cigarette

Do you know where the product was purchased? Yes

Do you know who manufactured this product? No

### **Product Purchase Location**

Purchase Location Name Holiday Oil Gas Station

Country United States

Street Address Line 1 <br/>
Street Address Line 2 <br/>
Street Address Line 3 <br/>
Street Address

City/Town (b)

State (b)

ZIP/Postal Code <blank>

Phone <blank>

How was this product purchased? in a store

Web Address <blank>

#### **Manufacturer Information**

Firm/Organization Name <blank>

Country <blank>

Phone <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Web Address <blank>

#### **Product Use Details**

1	When did the person open the package and start	
	using the product that may have caused the health problem?	<blank< td=""></blank<>

<blank>

When did the person stop using the product that may have caused the health problem?

How long has the person been using this brand? 1

Select Unit of Measure Months

Was the product being used when the health <blank> problem occurred?

Did the person use this product before without a problem?

Did the person change the product in any way before using it (for example: removing a filter from a cigarette)? No

Is the affected person currently using other tobacco products (within past month)?

Does the person who had the adverse event also Yes drink alcohol?

Has the affected person used other tobacco Yes products in the past?

How many drinks per week? 7+ drinks/ week

Please describe anything else you think the FDA should know about this health problem

There might be a product defect, but I'm not sure. It occasionally will have a burning sensation upon my lips, not in a chemical way, but in a way that suggests the heat from the heating mechanism is seeping through the edges of the portion of the cartridge that touches my lips.

On average, number of pieces, pinches, dips, or rubs used

Please select per month

On average, number of pinches used <blank>

Please select <blank>

#### Reaction and Product Relatedness

How soon after the product was last used did the health problem occur?

<blank>

Select Unit of Measure <blank>

Did the person stop using the product when he/she had the health problem?

### **Problem Summary**

Health problem start date 01/20/2014

Health problem end date 02/18/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time month(s)

Please describe the health problem or product problem:

I am not sure if there are compounding factors, but I thought I would report just in case it could lead to more reports/investigation. I had quit smoking and then a few months later, began to study for the Bar Examination. In an effort to not resume smoking cigarettes I began smoking an e-cigarette (high cartridge). I have noticed an increase in canker sores in my mouth and generally my lips have been more chapped/dry. The chapped lips may just be due to not ingesting enough fluids (as I am wont to do), but since it touches and concerns the same area I thought I would mention it. I do not recall the last time I had canker sores prior to this increase in e-cig use, but I have had approximately 6 in the last month. They tend to go away in a week, but a few have been simultaneous with others.

Do any of these apply to the health problem? (Select one or more)

None of the above

Outcome to date Ongoing

Was the person taken to an emergency facility?

Was the person evaluated by a healthcare

No professional?

Has the person had a similar health problem or

product problem?

Please describe the similar health problem or

<blank> product problem

What are the main symptoms or health problems? (select up to 5)

Redness, rash, swelling, blister or sore, Other problem not listed

### **Affected Person**

Gender Female

Pregnant No

Race (Select one or more) Asian, White

Ethnicity <blank>

Birth date of the person who experienced the health problem (b) (6)

Age of the person when the health problem occurred

Select Unit of Age year(s)

Please list any known pre-existing health Generally healthy. Had a diagnosis of rheumatoid arthritis in college, however, no effects from this in problems for the affected person the last 8 years or so. No other major health issues.

### **Product Components**

### **Other Products Used**

# **Other Tobacco Products Currently Used**

#### Other Tobacco Products Used in the Past

Brand Name or Product Name Camel Blue, Camel Platinum

Product Type Cigarettes

On average, number smoked 7

Please select per day

Duration of Use More than 12 months

# Medications, Vitamins and Supplements

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health

<blank>

#### **Attached Files**

None



# REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-02-21013:52:05

FDA ICSR ID (b) (6)

Followup by using your account (b) (6)

# Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

(b)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

### **Contact Information - Sender**

Confirm Email (b) (b) First Name (b) Last Name (b) Phone (b) (6) Email (b) (6) Country United States Street Address Line 1 (b) (6) Street Address Line 2 <blank> City/Town (b) State (b) ZIP/Postal Code (b) May the FDA contact you to follow-up if necessary? Preferred method of contact <blank> Sender Category Consumer/Concerned Citizen Are you the person who experienced health problems associated with a tobacco product? Please describe your relationship to the person <blank> who experienced the health problem

#### **Product Information**

### **Product Purchase Location**

#### Manufacturer Information

#### **Product Use Details**

When did the person open the package and start using the product that may have caused <blank> the health problem? When did the person stop using the product <blank> that may have caused the health problem? How long has the person been using this <blank> brand? Select Unit of Measure <blank> Was the product being used when the health <blank> problem occurred? Did the person use this product before without <blank> a problem? Did the person change the product in any way before using it (for example: removing a filter <blank> from a cigarette)? Is the affected person currently using other tobacco products (within past month)? Does the person who had the adverse event No also drink alcohol? Has the affected person used other tobacco No products in the past? Please describe anything else you think the <blank> FDA should know about this health problem On average, number of pieces, pinches, dips, <blank> Please select <blank>

#### **Reaction and Product Relatedness**

How soon after the product was last used did the health problem occur? <a href="https://doi.org/10.2016/j.jep.2016/">blank></a>

Select Unit of Measure week(s)

# **Problem Summary**

Health problem start date 01/10/2014

Health problem end date 02/21/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time week(s)

Please describe the health problem or product problem:

Employee inhales Vapors all day throughout office. One employee was out with respiratory illness, one has persistent cough and I ended up with bronchitis. I nor anyone in my family has ever smoked and yet in a month and a half 3 people have become ill since "vapors" were

introduced into our environment!

Do any of these apply to the health problem? (Select one or more)

Treatment Received

Outcome to date Ongoing

Was the person taken to an emergency facility? Yes

Was the person evaluated by a healthcare

professional?

Date the person was first seen by a healthcare 02/18/2014 professional for this health problem

Please describe any treatment the person received including results of any tests (such as Doxycycline and Hydrocodone-homatropine

x-rays, lab results, or blood work)

Has the person had a similar health problem or product problem?

Please describe the similar health problem or

product problem

What are the main symptoms or health problems? (select up to 5)

<u>Lungs or Breathing problem</u> (<i>such as: cough, asthma, wheezing, lung infection</i>)

### **Affected Person**

Gender Female

Pregnant No

Race (Select one or more) Unknown

Ethnicity Unknown

Birth date of the person who experienced the

(6) health problem

Age of the person when the health problem

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

### **Product Components**

Other Products Used

Other Tobacco Products Currently Used

Other Tobacco Products Used in the Past

# **Medications, Vitamins and Supplements**

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

<blank>

### **Attached Files**

None



# REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-02-26.16:06:48

FDA ICSR ID (b) (6)

Report Key for Followup (6) (6)

# **Report Identifying Information**

Create a name to help you find this report in the future (max length: 50 characters)

E-Cig (b) (6)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting? Both (health-related problem that is also associated with a product problem or defect)

### **Contact Information - Sender**

Confirm Email <blank>

First Name <blank>

Last Name <blank>

Phone <blank>

Email <blank>

Country United States

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State (b) (6)

ZIP/Postal Code <blank>

Check here if you wish to remain anonymous. Yes

May the FDA contact you to follow-up if necessary?

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product?

Please describe your relationship to the person who experienced the health problem

<blank>

#### **Product Information**

Brand Name or Product Name <blank>

Universal Product Code (UPC) from label <blank>

Did the product come from another country? <blank>

Product Type Other

When did the person purchase this product? <blank>

Does the person still have the product? Unknown

Description of other tobacco product type e-cigarette - vapor device

Do you know where the product was No

purchased?

Do you know who manufactured this product? No

#### **Product Purchase Location**

#### Manufacturer Information

### **Product Use Details**

When did the person open the package and start using the product that may have caused the health problem?	<black></black>
When did the person stop using the product that may have caused the health problem?	<blank></blank>
How long has the person been using this brand?	<blank></blank>
Select Unit of Measure <blank></blank>	
Was the product being used when the health problem occurred?	<blank></blank>
Did the person use this product before without a problem?	<black></black>
Did the person change the product in any way before using it (for example: removing a filter from a cigarette)?	<blank></blank>
Is the affected person currently using other tobacco products (within past month)?	No
Does the person who had the adverse event also drink alcohol?	No
Has the affected person used other tobacco products in the past?	No
Please describe anything else you think the FDA should know about this health problem	<black></black>
On average, number of pieces, pinches, dips, or rubs used	<black></black>
ATTO AND	

## **Reaction and Product Relatedness**

How soon after the product was last used did the health problem occur? <a href="https://doi.org/li>
</a> <a href="https://doi.org/li>
<a href="https://doi.org/li

Did the person stop using the product when he/she had the health problem? <br/>

# **Problem Summary**

Please select <blank>

Product Problem Type Appearance, look, smell or taste is wrong or not as expected, Child safety issue, Incorrect use - intentional (product was used incorrectly on purpose)

Health problem start date 02/25/2014

Health problem end date 02/25/2014

Product Problem Start Date 02/25/2014

Product Problem End Date 02/25/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time hour(s)

Please describe the health problem or product problem:

While eating dinner at (6) (6) last night in (6) , the person at the table nex to me was smoking one of those e-cigarettes. The vapor cloud was big enough to come over , the person at the table next my table and the e-cig smoker was 'huffing' it voraciously. I got dizzy, my eyes began to water and I ended up taking my food to go because of the intense heartbeat I began to develop. The vapor smelled/tasted like bubble gum and this idiot was huffing away with her kids at the table. I don't know if there are any laws against smoking these devices in public like there are for cigarettes/cigars/pipes but I would like to see you folks address this issue.

Do any of these apply to the health problem?

(Select one or more)

<blank>

Outcome to date Ongoing

Was the person taken to an emergency facility? No

Was the person evaluated by a healthcare

professional?

Has the person had a similar health problem or product problem?

Please describe the similar health problem or product problem

<blank>

No

What are the main symptoms or health problems? (select up to 5)

Tired, weak, dizzy, confused, feel bad/sick, <u>Lungs or Breathing problem</u> (<i>such as: cough, asthma, wheezing, lung infection</i>), <u>Mood or Mental health</u> problem (<i>such as: anxiety, agitation, depression</i>)

#### **Affected Person**

Gender Male

Race (Select one or more) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the health problem

(b)(6)

Age of the person when the health problem

occurred

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

## **Product Components**

#### Other Products Used

## Other Tobacco Products Currently Used

### Other Tobacco Products Used in the Past

# **Medications, Vitamins and Supplements**

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

<blank>

# **Attached Files**

None



# REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-02-26 22:44 04

FDA ICSR ID (b) (6)

Followup by using your account

(b) (6)

### Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

(b) (6) e-cigarette

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

### **Contact Information - Sender**

Confirm Email (b) (6) First Name (b) Last Name (b) Phone (b) (6) Email | (b) (6)Country United States Street Address Line 1 Street Address Line 2 <blank> City/Town (b) (6) State (b) ZIP/Postal Code (b) May the FDA contact you to follow-up if necessary? Preferred method of contact Email Sender Category Consumer/Concerned Citizen Are you the person who experienced health problems associated with a tobacco product? Please describe your relationship to the person who experienced the health problem

# **Product Information**

Brand Name or Product Name blu

Universal Product Code (UPC) from label <br/>
bid the product come from another country? Unknown

Product Type Other

When did the person purchase this product? O2/25/2014

Does the person still have the product? Yes

Description of other tobacco product type electronic cigarette

Do you know where the product was purchased?

Do you know who manufactured this product? No

# **Product Purchase Location**

Purchase Location Name Sunoco Gas Station

Country United States

Street Address Line 1 (b) (6

Street Address Line 2 <blank>

City/Town (b) (6)

State 0

ZIP/Postal Code (b)

Phone <blank>

How was this product purchased? in a store

Web Address <br/> <br/>

#### Manufacturer Information

#### **Product Use Details**

When did the person open the package and start using the product that may have caused 02/25/2014 the health problem?

When did the person stop using the product that may have caused the health problem?

<blank>

How long has the person been using this brand?

Select Unit of Measure Days

Was the product being used when the health problem occurred? Yes

Did the person use this product before without a problem?

Did the person change the product in any way before using it (for example: removing a filter No from a cigarette)?

Is the affected person currently using other tobacco products (within past month)?

Does the person who had the adverse event also drink alcohol?

Has the affected person used other tobacco products in the past? No

How many drinks per week? 7+ drinks/ week

Please describe anything else you think the FDA should know about this health problem

On average, number of pieces, pinches, dips, or rubs used

Please select per day

### **Reaction and Product Relatedness**

How soon after the product was last used did the health problem occur?

Select Unit of Measure hour(s)

Did the person stop using the product when he/she had the health problem?

Did the symptoms from the health problem go away or get better when the person stopped or reduced the amount of product used?

Did the person start using the product again? No

How long was it before the person started using the product again?

<blank>

Select Unit of Measure <blank>

Did the health problem happen again after the person started using the product again?

Not Applicable

## **Problem Summary**

Health problem start date 02/26/2014

Health problem end date <blank>

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time hour(s)

Please describe the health problem or product problem:

My fiancé started using blu electronic cigarette starter kit, original flavor at 3pm on Tuesday, 2/25/14. Over the night, his lips swelled to twice their normal size and became extremely painful. Further, all his joints throughout his body hurt and ache to a debilitating point. It is difficult for him to walk. His hands and forearms itch and are red and burning.

Do any of these apply to the health problem? (Select one or more)

None of the above

Outcome to date Ongoing

Was the person taken to an emergency

facility?

Was the person evaluated by a healthcare professional?

Has the person had a similar health problem or product problem?

Please describe the similar health problem or product problem

<blank>

What are the main symptoms or health problems? (select up to 5)

Redness, rash, swelling, blister or sore, Pain, numbness, itching or unusual sensation, Tired, weak, dizzy, confused, feel bad/sick, <u>Allergic</u> reaction, <u>Digestive System</u> problem (<i>such as: nausea/vomiting, stomach pain, diarrhea, constipation</i>)

#### **Affected Person**

Gender Male

Race (Select one or more) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the health problem

(b) (6)

Age of the person when the health problem occurred

Select Unit of Age year(s)

Please list any known pre-existing health <blank> problems for the affected person

**Product Components** 

**Other Products Used** 

Other Tobacco Products Currently Used

Brand Name or Product Name Marlboro

Product Type Cigarettes

On average, number smoked 18

Please select per day

Duration of Use More than 12 months

Other Tobacco Products Used in the Past

Medications, Vitamins and Supplements

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

**Attached Files** 

FILENAME (b) (6)

Description of Attachment

(b) (6)

Attachment Type Photograph

B6: One page withheld because it contains individual privacy identifier.



# REPORT INFORMATION

### **Report Profile**

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-02-28 16:11:58

FDA ICSR ID (b) (6)

Report Key for Followup (b) (6)

# Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

e-cigs(b) (6)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

#### **Contact Information - Sender**

Confirm Email <blank>

First Name <blank>

Last Name <blank>

Phone <blank>

Email <blank>

Country United States

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State (b) (6)

ZIP/Postal Code <blank>

Check here if you wish to remain anonymous. Yes

May the FDA contact you to follow-up if <blank>

necessary?

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product?

Yes

Please describe your relationship to the person who experienced the health problem

#### **Product Information**

Brand Name or Product Name <blank>

Did the product come from another country? Unknown

Product Type Cigarettes

When did the person purchase this product? <blank>

Does the person still have the product? Unknown

Do you know where the product was purchased? No

Do you know who manufactured this product? No

#### **Product Purchase Location**

### **Manufacturer Information**

#### **Product Use Details**

When did the person open the package and start using the product that may have caused the health problem?

<blank>

When did the person stop using the product that may have caused the health problem?

<blank>

How long has the person been using this brand? <blank>

Select Unit of Measure <blank>

Was the product being used when the health problem occurred?

Yes

Did the person use this product before without a

problem?

Unknown

Did the person change the product in any way before using it (for example: removing a filter from a cigarette)?

Unknown

On average, number smoked <blank>

Please select <blank>

#### Reaction and Product Relatedness

How soon after the product was last used did <blank> the health problem occur?

Select Unit of Measure <blank>

Did the person stop using the product when he/she had the health problem?

<blank>

### **Problem Summary**

Health problem start date 02/26/2014

Health problem end date 02/27/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time hour(s)

Please describe the health problem or product problem:

I was sitting next to a person who was puffing on an e cigarette for a few hours in a closed room and developed bad headache, inflamed sinuses and eye irritation. I left work sick and symptoms did not resolve for about 24 hours. The day after, my throat became sore and now I have cold like symptoms.

Do any of these apply to the health problem? (Select one or more)

None of the above

Outcome to date Unknown

Was the person taken to an emergency facility? No

Was the person evaluated by a healthcare professional?

No

Has the person had a similar health problem or

product problem?

Please describe the similar health problem or product problem

<blank>

problems? (select up to 5)

What are the main symptoms or health Pain, numbness, itching or unusual sensation, Tired, weak, dizzy, confused, feel bad/sick. <u>Allergic</u> reaction

### **Affected Person**

Gender Male Race (Select one or more) White Ethnicity Not Hispanic or Latino Birth date of the person who experienced the (b) (6) health problem Age of the person when the health problem Select Unit of Age year(s) Please list any known pre-existing health problems for the affected person **Product Components** Component Type Cigarettes **Component Purchase Location Component Manufacturer Information Product Components** Component Type Menthol **Component Purchase Location Component Manufacturer Information Product Components** Component Type FSC paper

**Component Purchase Location** 

component Manufacturer Information	_
roduct Components  Component Type Flavoring	_
Component Purchase Location	
component Manufacturer Information	
Component Type Other	_
component Purchase Location	
component Manufacturer Information	
Other Products Used	
Other Tobacco Products Currently Used	
Other Tobacco Products Used in the Past	
Medications, Vitamins and Supplements	
ttached Files	

None



## REPORT INFORMATION

#### Report Profile

Report Version FPSR FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-03-01016:15:09

FDA ICSR ID (b) (6)

Report Key for Followup (b) (6)

## Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

(b) (6)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

#### Contact Information - Sender

Sender Category Consumer/Concerned Citizen

#### **Product Information**

Brand Name or Product Name <blank>

Universal Product Code (UPC) from label <blank>

Did the product come from another country? <blank>

Product Type Other

When did the person purchase this product? <blank>

Does the person still have the product? <blank>

Description of other tobacco product type Electronic cigarette vapor

Do you know where the product was <blank>

purchased?

Do you know who manufactured this product? <blank>

#### Product Purchase Location

#### Manufacturer Information

#### **Product Use Details**

When did the person open the package and start using the product that may have caused <blank> the health problem?

When did the person stop using the product <blank> that may have caused the health problem?

How long has the person been using this <blank> brand?

Select Unit of Measure <blank>

Was the product being used when the health <blank> problem occurred?

Did the person use this product before without <blank> a problem?

Did the person change the product in any way before using it (for example: removing a filter <blank> from a cigarette)?

On average, number of pieces, pinches, dips, <blank> or rubs used

Please select <blank>

#### **Reaction and Product Relatedness**

How soon after the product was last used did <blank> the health problem occur?

Select Unit of Measure <blank>

Did the person stop using the product when he/she had the health problem? <blank>

#### **Problem Summary**

Health problem start date 11//2013

Health problem end date <blank>

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted 3

Select Unit of Time month(s)

Please describe the health problem or product problem:

Year long exposure to e cigarette second hand vapor

Do any of these apply to the health problem?

None of the above (Select one or more)

Outcome to date Ongoing

Was the person taken to an emergency No

facility?

Was the person evaluated by a healthcare

professional?

12//2013

Date the person was first seen by a healthcare

professional for this health problem

Please describe any treatment the person

received including results of any tests (such

as x-rays, lab results, or blood work)

Chest X-ray, received corticosteroid for few days

Has the person had a similar health problem

or product problem?

Please describe the similar health problem or

product problem

Ongoing coughs on varying days

What are the main symptoms or health

problems? (select up to 5)

<u>Lungs or Breathing problem</u> (<i>such as: cough, asthma, wheezing, lung infection</i>)

#### Affected Person

Gender <blank>

Race (Select one or more) Unknown

Ethnicity <blank>

Birth date of the person who experienced the health problem

(b) (6)

Age of the person when the health problem occurred 45	
Select Unit of Age year(s)	
Please list any known pre-existing health problems for the affected person	
Product Components	The A Company of the Street on
Other Products Used	
	And anticological control
Other Tobacco Products Currently Used	
Other Tobacco Products Used in the Past	
	A STATE OF THE STA
Medications, Vitamins and Supplements	
Attached Files	The most action to a second
None	



## REPORT INFORMATION

#### **Report Profile**

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-03-03017:47:56

FDA ICSR ID (b) (6)

Report Key for Followup

(b) (6)

#### Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

E Cigarettes (b) (6)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

#### **Contact Information - Sender**

Confirm Email (b) (6)

First Name (b)

Last Name (b)

Phone <blank>

Email (b) (6)

Country United States

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State (b)

ZIP/Postal Code <biank>

Check here if you wish to remain anonymous. <blank>

May the FDA contact you to follow-up if necessary?

Preferred method of contact Email

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product?

Please describe your relationship to the person who experienced the health problem <br/>

#### **Product Information**

Brand Name or Product Name some type of e-cigarette product

Did the product come from another country? <blank>

Product Type Cigarettes

When did the person purchase this product? <blank>

Does the person still have the product? Unknown

Do you know where the product was purchased? No

Do you know who manufactured this product? No

#### **Product Purchase Location**

#### **Manufacturer Information**

#### **Product Use Details**

When did the person open the package and start using the product that may have caused the

<blank> health problem?

When did the person stop using the product that may have caused the health problem?

<blank>

How long has the person been using this brand? <blank>

Select Unit of Measure <blank>

Was the product being used when the health problem occurred?

<blank>

Did the person use this product before without a

Unknown

Did the person change the product in any way before using it (for example: removing a filter

from a cigarette)?

Unknown

Is the affected person currently using other tobacco products (within past month)?

<blank>

Does the person who had the adverse event also drink alcohol?

<blank>

Has the affected person used other tobacco products in the past?

<blank>

On average, number smoked <blank>

Please describe anything else you think the FDA I do not smoke, none of the product usage questions pertain to me. I was a bystander being forced should know about this health problem to work in an environment where others used e-cigarettes.

Please select <blank>

#### Reaction and Product Relatedness

How soon after the product was last used did the health problem occur?

<blank>

Select Unit of Measure <blank>

Did the person stop using the product when he/she had the health problem?

#### **Problem Summary**

Health problem start date 02/03/2014

Health problem end date 02/21/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)?

Select Unit of Time week(s)

As an employee with the (b) (6) , I was forced to sit in an office where people used ecigarettes (indoors) exposing everyone to the vapor. I noticed side-effects through secondhand inhalation within the first week of this exposure. I complained about difficulty breathing and having bloody noses to my boss. These symptoms did not exist prior to the exposure. After I complained and was exposed to the vapor for 3 weeks, with the symptoms continuing, I told my boss to either move me to another office or stop the workers from smoking the e-cigarettes inside our office. Well, I was fired from my job! The good news is that after I was fired, and no longer exposed to the vapor, my symptoms were not noticeable after about 2-3 days. I know it was the exposure to the vapor that caused my illness because the new office and vapor exposure was the only thing different in my environment for that period. The vapor from those e-cigarettes is toxic, and the e-cigarette is NOT safe for bystanders. If you need more details, please contact me.

Please describe the health problem or product problem: Outcome to date Unknown

Do any of these apply to the health problem? <blank> (Select one or more)

Was the person taken to an emergency facility? No

Was the person evaluated by a healthcare professional?

Has the person had a similar health problem or product problem?

Please describe the similar health problem or <blank> product problem

What are the main symptoms or health Tired, weak, dizzy, confused, feel bad/sick, <u>Lungs or Breathing problem</u> (<i>such as: cough, problems? (select up to 5) asthma, wheezing, lung infection</i>)

#### **Affected Person**

Gender Female

Pregnant No

Race (Select one or more) White

Ethnicity <blank>

Birth date of the person who experienced the <blank>

health problem

Age of the person when the health problem <blank>

occurred

Select Unit of Age <blank>

Please list any known pre-existing health problems for the affected person

I do not have pre-existing conditions.

#### **Product Components**

Component Type Cigarettes

#### **Component Purchase Location**

#### **Component Manufacturer Information**

#### **Product Components**

Component Type Menthol

#### **Component Purchase Location**

Component Manufacturer Information		
Product Components  Component Type FSC paper	and you be	appoint on
Component Purchase Location		San re or - r
Component Manufacturer Information		2.1.9
Product Components  Component Type Flavoring		
Component Purchase Location		-
Component Manufacturer Information		
Product Components  Component Type Other	_	
Component Purchase Location		
Component Manufacturer Information		
Other Products Used		

Other Tobacco Products Currently U	sea
------------------------------------	-----

Other Tobacco Products Used in the Past

#### Medications, Vitamins and Supplements

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

#### **Attached Files**

None



## REPORT INFORMATION

## **Report Profile**

Report Version FPSR.FDA.CTP.V.V1

Report Category Tobacco Product Report

Submitted 2014-03-12 14:48:52

FDA ICSR ID (b) (6)

Report Key for Followup

(b) (6)

#### Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)

E Cigarette

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting?

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

#### **Contact Information - Sender**

Confirm Email (b) (6)	
First Name (b)	
Last Name (b)	
Phone (b) (6)	
Email (b) (6)	
Country United States	
Street Address Line 1 (b) (6	)
Street Address Line 2 <blank></blank>	
City/Town (b) (6)	
State (b)	
ZIP/Postal Code (b)	
Check here if you wish to remain anonymous.	<blank></blank>
May the FDA contact you to follow-up if necessary?	Yes
Preferred method of contact Email	
Sender Category Consumer/Concerned Citize	n
Are you the person who experienced health problems associated with a tobacco product?	Yes
Please describe your relationship to the person who experienced the health problem	<blank></blank>

#### **Product Information**

Brand Name or Product Name Sweet Southern Vapes

Universal Product Code (UPC) from label <br/>
bid the product come from another country? Unknown

Product Type Other

When did the person purchase this product? 02/20/2014

Does the person still have the product? Yes

Description of other tobacco product type Electronic Cigarette

Do you know where the product was purchased? Yes

Do you know who manufactured this product? No

#### **Product Purchase Location**

Purchase Location Name flea market

Country United States

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town (b) (6)

State (b)

ZIP/Postal Code (b)

Phone <blank>

How was this product purchased? in a store

Web Address <blank>

#### **Manufacturer Information**

#### **Product Use Details**

When did the person open the package and start using the product that may have caused 02/20/2014 the health problem?

When did the person stop using the product that may have caused the health problem? <br/>

How long has the person been using this brand?

Select Unit of Measure Weeks

Was the product being used when the health problem occurred? Yes

Did the person use this product before without a problem?

Did the person change the product in any way before using it (for example: removing a filter No from a cigarette)?

Please select <blank>

#### **Reaction and Product Relatedness**

How soon after the product was last used did the health problem occur?

Select Unit of Measure day(s)

Did the person stop using the product when he/she had the health problem?

#### **Problem Summary**

Health problem start date 03/11/2014

Health problem end date <blank>

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted 2 so far)?

Select Unit of Time day(s)

Please describe the health problem or product problem:

My husband had purchased an Electronic Cigarette and apparently he was told they are safe and the vapor is just like water so he thought it would be safe to smoke anywhere in the car and in the house but apparently they are not my 4 year olds has had a raspy voice since he started but I really didn't think anything of it till last night my husband was just puffing away on that thing for hours and I woke up wheezing and unable to breath I thought I was going to have to go to the hospital or just die I felt like I was breathing through a straw. I sat outside for a little and coughed up mucus. I am still wheezing today but it's not as bad. I don't have any history of breathing problems that why it was just so strange. Also my husband has been having trouble hearing and has lost his voice three times since he got it. I just want to report this because I know there is not much known about those things and I think they should caution people about the side effects before being allowed to sell them.

Do any of these apply to the health problem?

<blank> (Select one or more)

Outcome to date Ongoing

Was the person taken to an emergency facility? No

Was the person evaluated by a healthcare professional?

Has the person had a similar health problem or product problem?

Please describe the similar health problem or product problem

> What are the main symptoms or health problems? (select up to 5)

<u>Allergic</u> reaction, <u>Lungs or Breathing problem</u> (<i>such as: cough, asthma, wheezing, lung infection</i>), <u>Head or Neck</u> problem (<i>such as: difficulty swallowing; change in speech, taste, hearing or vision; seizure, stroke</i>), Non-user or child was harmed or injured (includes accidental use or swallowing by a child)

#### **Affected Person**

Gender Female

Pregnant No

Race (Select one or more) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the health problem

(b) (6)

<blank>

Age of the person when the health problem

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person

None

#### **Product Components**

#### Other Products Used

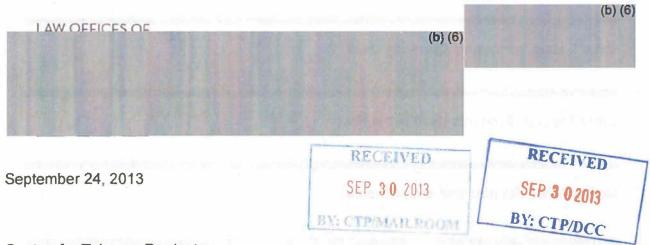
Other Tobacco Proc	lucts Currently Used
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Other Tobacco Products Used in the Past

Medications, Vitamins and Supplements

#### **Attached Files**

None



Center for Tobacco Products
Document Control Center, Room 020J
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: Electronic Cigarettes

I read an article on Time Magazine's 9/30/13 issue about electronic cigarettes and I believe this product should be strictly regulated. The liquid that is sold at the stores that carry electronic cigarettes are sold over the counter without a prescription or any sort of regulation although they are extremely addictive.

My daughter started purchasing the liquid for her electronic cigarettes and ended up using it or drinking it until she got totally addicted to the extent that she ended up in the emergency room at UCLA several weeks ago in a psychotic condition. This substance is a narcotic and should be regulated as such rather than sold as another cigarette. It is very concentrated and electronic smoking is described as a great experience. Please look into it and I am very willing to give you additional information if requested.

Very truly yours,

U.S. Department of Health and Human Services

The FDA Safety information and **Adverse Event Reporting Program** 

C. PRODUCT AVAILABILITY

D. SUSPECT PRODUCT(S)

(b)

Check all that apply

TYPE OR USE BLACK

EA

7

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

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

Consumer

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

FDA USE ONLY

Triage unit

sequence #

dverse Event Reporting Program	e I OT Z	1120	
A. PATIENT INFORMATION	2. Dose or Amount	Frequency	Route
Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight	#1 OTC	As needed	Inhalation
(b) Date of Birth: 184 b			
(b) (6)	#2		
In confidence			
3. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR nock all that apply.	3. Dates of Use (If unknown (or best estimate)	wn, give duration) from/to	5 Event Abated After Use Stopped or Dose Reduced?
Adverse Event Product Problem (e.g., defects/malfunctions)	#1 09/07/2013 - 10	/26/2013	#1 Yes No Doesn
Product Use Error Problem with Different Manufacturer of Same Medicin	#2		
Outcomes Attributed to Adverse Event	4. Diagnosis or Reason	Control of the Contro	Apply
(Check all that apply)	#1 smoking cessa	tion	8. Event Reappeared After Reintroduction?
Death: Disability or Permanent Damage	#2		#1 Yes No Doesn
Life-threatening Congenital Anomaly/Birth Defect			Apply
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events	6. Lot#	7. Expiration Date	#2 Yes No Doesr
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	#1 N/A	#1	9. NDC # or Unique ID
Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)	#2	#2	N/A
10/26/2013 10/26/2013	E. SUSPECT MED	ICAL DEVICE	
Describe Event, Problem or Product Use Error	1. Brand Name		
After 2 months use of E-Cig Vaporizer PEG 1) 2 weeks chronic diahrea 2) progressive acute dermal			
inflamation of the entire chin area spreading to the	2. Common Device Name	•	
face and scalp 3) renal impairment progressed to direct and immediate effect as per doseage use. Have	11		
immediately ceased and am seeking ways to purge	3. Manufacturer Name, C	ity and State	
system. Please answer IMMEDIATELY with information as to treatment protocol (b) (6)		- 1	
(b) (6)			
	4. Model #	Lot#	5. Operator of Device
			Health Profession
	Catalog #	Expiration Date (m	m/dd/yyyy)    Lay User/Patient
			Other:
Relevant Tests/Laboratory Data, Including Dates	Serial #	Other#	of the last to
symptoms apparent 2 weeks ago, isolated and confirmed 10/26/13 ceased use today			
1) chronic diahrea for 2 weeks	6. If Implanted, Give Date	(mm/dd/yyyy) 7. If Ex	planted, Give Date (mm/dd/yyy/
<ol><li>developed chin rash 1 week ago, spread and worsening.</li></ol>			
the season of th		vice that was Reprocess	sed and Reused on a Patient?
Drinking fluids, treating diahrea, seeking antidotes. Will begin organic natural vitamin C 4.800MDA and	Yes No 9. If Yes to Item No. 8, Ent.	or Name and Address of D	Annocarear
and any other first the state of the state o	. It too to well No. 6, End	Address of K	-processor
Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)	CONCARA I NA		
Race: White Medical Conditions: high blood pressure,	F. OTHER (CONCC	MITANTI MEDICAL	PRODUCTS
cardiac stent, CAD, PAD, kidney disease	Product names and then		
symptoms easing with increased allery meds, cortizone,	The state of the s		•
Loperamide Hydrochloride Allergies: life long chemical, food and environmental,			
Contact info: (b) (b)			
Symtomology:	G. REPORTER (See	confidentiality sect	ion on back)
. PRODUCT AVAILABILITY	1. Name and Address		(6) (6)
	THE RESERVE OF THE PARTY OF THE		(b) (6)
roduct Available for Evaluation? (Do not send product to FDA)			
roduct Available for Evaluation? (Do not send product to FDA)			
roduct Available for Evaluation? (Do not send product to FDA)  Yes No Returned to Manufacturer on:(mm/dd/yyyy)			
roduct Available for Evaluation? (Do not send product to FDA)  // Yes No Returned to Manufacturer on: (mm/dd/yyyy)  SUSPECT PRODUCT(S)	Phone #	E-mail	
roduct Available for Evaluation? (Do not send product to FDA)  // Yes No Returned to Manufacturer on: // (mm/dd/yyyy)  SUSPECT PRODUCT(S)  Name, Strength, Manufacturer (from product label)		E-mail	(b) (6)
roduct Available for Evaluation? (Do not send product to FDA)  // Yes No Returned to Manufacturer on: (mm/dd/yyyy)  SUSPECT PRODUCT(S)	(b) (6)		(b) (6)
roduct Available for Evaluation? (Do not send product to FDA)  Yes No Returned to Manufacturer on: (mm/dd/yyyy)  SUSPECT PRODUCT(S)  Name, Strength, Manufacturer (from product label)  Name: E-Cig Juice PEG formula	(b) (6)  2. Health Professional?		(b) (6)
roduct Available for Evaluation? (Do not send product to FDA)  Yes No Returned to Manufacturer on: (mm/dd/yyyy)  SUSPECT PRODUCT(S)  Name, Strength, Manufacturer (from product label)  Name: E-Cig Juice PEG formula  Strength: 16mg nic Manufacturer: CreateACig.com  Name:	2 Health Professional?	3. Occupation	4. Also Reported to:  Manufacturer
roduct Available for Evaluation? (Do not send product to FDA)  Yes No Returned to Manufacturer on: (mm/dc/yyyy)  SUSPECT PRODUCT(S)  Name, Strength, Manufacturer (from product label)  Name: E-Cig Juice PEG formula  Strength: 16mg nic Manufacturer: CreateACig.com	(b) (6)  2. Health Professional?	Occupation  Identity disclosed	4. Also Reported to:  Manufacturer  User Facility

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#2 Name: Strength: Manufacturer:

## MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

#### (CONTINUATION PAGE)

For VOLUNTARY reporting of adverse events and product problems

Page 2 of 2

B.5. Describe Event or Problem (continued)	
Cont. (1988)	
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)	
B.b. Relevant Tests/Laboratory Data, Including Dates (continued) MDA	
MDA	
107	
A CANADA IN TARABLE DE	
erials of the eight and the party	
e	
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies,	race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
PEG (polyethelene glycol) toxicity Important Inf Missing info previous page: ceasing use yesterday an Result some easing of symptoms Symtomology: PEG (polyethelene glycol) toxicity RX M plavix, nexium, hctz, chlorzoxazone, tramadol Symtomology: PEG (polyethelene glycol) toxicity OTC poppy, stinging nettles, afrin, L-Lysine, Zyrtec, Cl Symtomology: PEG (polyethelene glycol) toxicity	ded today, cortizone, increased allergy doseage.  Meds: metropolol, lisinopril, pravastatin, Zetia,  Meds: asprin, melatonin, holy basil, clifornia
The second secon	
*	
	newe yet and a second of the s
F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (cont	tinued)



U.S. Department of Health and Human Services MEDWATCH

FORM FDA 3500 (1/09)

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

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

Triage unit

	Information and Reporting Program		Page	1 of 2			
			, ugc	2. Dose or Amount	Frequen	cy Route	
A. PATIENT IN	FORMATION  2. Age at Time of Event of	or 13. Sex	4. Weight	2. Dose or Amount	r requen	Kouta	
))	Date of Birth:		270 lb	K-100			
	59 Years	▼ Female	270 lb	#2	===		
la confidence	(b) (6)	☐ Male	or kg		1		
In confidence	EVENT, PRODUCT F	PORI EM OP E	PPOP	3. Dates of Use (If unknown	n give duration)	from/to 5 Even	t Abated After Use
heck all that apply:	ZVENT, FRODUCT F	NODECHI ON E	KKOK	(or best estimate)	give amanery		d or Dose Reduced
. Adverse Even	t Product Problem	(e.g., defects/malfun	ctions)	#1		#1 🕢 ነ	res No Do
Later 1	mor Problem with Diff	ferent Manufacturer	of Same Medicine	#2		₩ []\	
2. Outcomes Attrib	uted to Adverse Event	-		4. Diagnosis or Reason fo	or Use (Indication	n)	Ap
(Check all that ap)	oly)			#1 Bystander subj		Dalmi	t Reappeared After roduction?
Death:	mm/dd/yyyy)	isability or Permanen	l Damage	hand "vapor sm	oke" Irom e		res No Do
Life-threatening		ongenital Anomaly/Bi	rth Defect	"-			Ap
Hospitalization	- initial or prolonged 0	ther Serious (Importa	nt Medical Events)	6. Lot #	7. Expiration	Date #2	res No Do
	vention to Prevent Permane			#1	#1	9. NDC	# or Unique ID
3. Date of Event (m	m/dd/www) 4	Date of this Report (	mm/dd/www)	#2	#2		
10/02/2013		0/25/2013	*****	E. SUSPECT MEDIC	CAL DEVICE	ROLL BUTTON	TO BEST ON
The party of the p	Problem or Product Use 8			1. Brand Name			
I have sever	e COPD and I also	have heart th					
problems. I	was waiting in li get a RX filled.	ne at a local	CVS	2. Common Device Name			
	get a KX fiffed.			2. Common Device Name			
of my left s	houlder. I starte	d feeling dizz	y and a bit				
	nd my heart starte I sweating somewha			3. Manufacturer Name, Ci	ty and State		
	copiously and pro			11			
	nd exhaling the "v						
	nat it was she was narmless vapor bei			4. Model #	Lot#		5. Operator of De
	't as harmless						Health Profess
				Catalog #	Fundan	Data (mar/datinas)	Di aution/Dava
				Catalog » Expiration Date (no		Date (mm/dd/yyyy)	Lay User/Patie
							Other:
6. Relevant Tests/L	aboratory Data, Including	Dates		Serial #	Other#	The state of	-
				6. If Implanted, Give Date	(mm/dd/yyyy)	7. If Explented, G	Hve D≘te (mm/dd/yy
				8. Is this a Single-use Dev	rice that was Re	processed and Re	used on a Patient?
				Yes No		(D.	-
				9. If Yes to Item No. 8, Enter	r Name and Addr	ess of Reprocessor	
. Other Relevant H	istory, Including Preexist	ing Medical Condition	ons (e.g.,	11			
Race: White	gnancy, smoking and alco dedical Conditions	noruse, Ever/Ridney p	rhythm	E OTHER SOUR	A COM A A LONG OF	DIGAL SEC	1070
problems, Ha	ashimoto's Allerg	ies: Zantac, I	ovenox,	F. OTHER (CONCO			
	d bee stings Impor alcohol. Arthriti		on: No	Product names and therap	py dates (exclud	le treatment of ever	18)
	ne, CPAP OTC Meds		spirin,				
Centrum Sil							
				G. REPORTER (See	confidential	ly section on b	ack)
				1. Name and Address	commutantiali	ty section on b	uchy
C. PRODUCT A				(b) (6)	NU. B. O'M	A STATE OF THE PARTY OF	
Product Available f	or Evaluation? (Do not ser	nd product to FDA)					13 15 15 15
Yes No	Returned to Manufac	turer on:	Volchoend	CONTRACTOR OF THE PARTY OF THE			Design of the
SUSPECT P	RODUCT(S)	(mn	Vdd/yyyy)	EUG BEEFERE			
	Manufacturer (from produc	ct (abel)	100000000000000000000000000000000000000	Phone #	- 1	E-mail	
1 Name: e-ciga				(b) (6)		(b) (6)	
Strength: unknown	own						
Manufacturer: ut	nknown			2. Health Professional? 3	Occupation -	4	. Also Reported to:
2 Name:				Yes No			Manufacturer
Strength:				5. If you do NOT want your to the manufacturer, place			User Facility Distributor/Impo

#### (CONTINUATION PAGE)

# For VOLUNTARY reporting of adverse events and product problems

Page 2 of 2

The FDA Safety Information and Adverse Event Reporting Program

B.5. Describe Event or Problem (continued) as she convinced herself it was. I was beginning to go into a crisis because of her exhaled "vap smoke." When she left and the air cleared, my problem also cleared. I don't think these e-cigarettes are as "harmless" as they are touted to be. I had no issues before she blew the vapor smoke in my fall did have systemic issues when she did do so. After the air cleared, the symptoms I had also cleared						
up.	a city was any and a line					
up.						
	and the law are a significant					
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) (con	ntinued					
to a supplimite measure a sandar and the obly a sand faminers as a supplied to	nurued)					

U.S. Department of Health and Human Services

# For VOLUNTARY reporting of

The FDA Safety Information and **Adverse Event Reporting Program** 

**b**)

Check all that apply:

BI

USE

OR TYPE (

EASE d 3 Date of Event (mm/dd/yyyy)

adverse events, product problems and product use errors

Page

Form Approved:	OMB			12/31/2011 on reverse
AND DESIGNATION OF THE PERSON	FDA	us	E ONLY	WINE !

Triage unit sequence #

dverse Event Reporting Program	Page 1	of 2				
A. PATIENT INFORMATION	A 142 133	2. Dose or A	mount	Frequency	Route	
Patient Identifier 2. Age at Time of Event or Date of Birth:	4. Weight 127 lb	#1				
(b) (6) Femal	eib	#2		-		
In confidence Male	lor kg					
B. ADVERSE EVENT, PRODUCT PROBLEM OR heck all that apply:		3. Dates of Use (or best estim	(If unknown, gi	ve duration) fr	Stopped	Abated After Use or Dose Reduced?
Product Use Error Problem (e.g., defects/mail		#2				Apply
Outcomes Attributed to Adverse Event	of Of Came Medicare	4. Diagnosis or	Reason for Us	se (Indication)	#2 Y	es No Doesn't
(Check all that apply)		#1				Reappeared After oduction?
Death: Disability or Perman		#2			#1 🗆 Y	es No Doesn't
Life-threatening Congenital Anomaly		6. Lot#	7	Expiration Da	#2 TY	es No Doesn't
Hospitalization - Initial or prolonged Other Serious (Impo		#1	#1			Apply for Unique ID
Date of Event (mm/dd/yyyy) 4. Date of this Repo		#2	#2	2		•
10/06/2013 11/12/2013		E. SUSPEC	T MEDICAL	L DEVICE	H. Transfer	NO STATES
Describe Event, Problem or Product Use Error		1. Brand Name				
I am a 58 year old female, healthy, nonsm recently spent time socially in a place w						
"e-cigarettes" were being used. It took me while to figure out that the sudden dizzi		2. Common De	vice Name			
difficulty breathing I was experiencing w	as related to					
the "harmless vapor" that the smokers were was using a menu to fan away the vapor the		3. Manufacture	r Name, City a	nd State		
could (they all thought I had a 6 hour lo Haha!) but by the end of the evening my t		-				
sore and constricted, my breathing impair	ed, and my	4. Model #		Lot#		5. Operator of Device
clothing smelled of the sicky sweet scent various products in use. It	of the	7. 1800001 19		LOT W	1	Health Professional
		Catalan #		Fundamenta - D		
		Catalog #		Expiration U	ate (mm/od/yyyy)	Lay User/Patient
Relevant Tests/Laboratory Date, Including Dates		Contat #		04		Other:
Title verification and the second an		Serial #		Other#	-4	
		C Minimalantad	Chia Data (ann	o felella and T	7 M.F. wheeled C	ba Bata (market)
		6. If implanted,	Give Date (min	voavyyyy)	/. If Explanted, G	ive Date (mm/dd/yyyy)
		8. is this a Sing		that was Rep	rocessed and Re	used on a Patient?
				me and Addres	s of Reprocessor	
Other Patricipat History, Institution Description Madical Cons	Mile /					
Other Relevant History, including Preexisting Medical Cond allergies, race, pregnancy, smoking and alcohol use, liver/kidne	y problems, etc.)					
Race: Medical Conditions: Allergies: Information: RX Meds: OTC Meds:	Important				ICAL PRODU	
		Product names	and therapy d	lates (exclude	treatment of even	n
				nfidentiality	section on ba	ack)
. PRODUCT AVAILABILITY	HOLLING!	1. Name and Ar Name: (b) (	6)			
roduct Available for Evaluation? (Do not send product to FDA)	)	Address:		_		
Yes No Returned to Manufacture; on:	(mm/dd/yyyy)				(6)	(h) (6)
SUSPECT PRODUCT(S)		City:			State (b) ZII	(0) (0)
Name, Strength, Manufacturer (from product label)	-1-	Phone # (b) (6)	-		E-mail b) (6)	
Mame: e-cigarette Strength:			No.			
Manufacturer:		2. Health Profe		cupation	4.	Also Reported to:
Name:		Yes Yes		Albertaine .		Manufacturer User Facility
Strength: Manufacturer:		5. If you do NOT to the manufa	i want your iden icturer, place an		ж: 🗌	Distributor/importer

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#1 Name: e-cigarette Strength: Manufacturer: #2 Name: Strength Manufacturer:

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 Service

MEOWATCH
The EDA Safety Information and

# (CONTINUATION PAGE) For VOLUNTARY reporting of adverse events and product problems

The FDA Safety Information and Adverse Everit Reporting Program	Page 2 of 2
B.5. Describe Event or Problem (continued)	
are "secondhand smoke" issues for us	o heal and my breathing to be normal. I am convinced that there non smokers in closed environments when these devices are in use
My request is that these issues be sto these devices as a health issue for the	udied and that non-smoking establishments will restrict the use he non-users. Thank You, (b) (6)
the Age of the Contraction of	
PACHTO HAT	
B.6. Relevant Tests/Laboratory Data, Including Dates (continu	ued)
- 114 -	
B.7. Other Relevant History, Including Preexisting Medical Co	onditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued
F. Concomitant Medical Products and Therapy Dates (Exclude	le treatment of event) (continued)

U.S. Department of Health and Human Services

Internet Consumer Report

# CTP

Triage unit sequence #

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## MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

See OMB statement on reverse
FDA USE ONLY

A STATE OF THE PARTY OF THE PAR	nt Reporting Progr	ati)			11/					
The same of the sa	INFORMATION	The latest	Water State of the	2. D	lose or Amount	Frequ	ency	Route		
1. Patient Identif.	or 2. Age at Time of E Date of Birth:	vent or 3. Sex	4. Weight	"						
, (0)	19 Years	Female	lb	#2 [						
In confidence	<b>(b)</b> (6)	✓ Male	or kg				-			
	E EVENT. PRODU	CT PROBLEM OR E	RROR	3. Data	es of Use (If unkno	wn, give duration	an) from/to	5. Event	Abated Aft	er Use
Check all that app				11	best estimate)	. /			or Dose R	
1. Adverse Ev	rent Product Pro	blem (e.g., defects/malfu	nctions)	-	/08/2013 - 11	1/17/2013	1	#1 Y	es 🗸 No	Does Apply
Product Us	e Error Problem wit	h Different Manufacture	r of Same Medicine					#2 TY	es No	Does
2 Outcomes Att	ributed to Adverse Eve	nt			gnosis or Reason to quit smoking			8 Event	Reappeare	Apply Apply
Death:	appiyy	Disability or Permane	nt Damage		etter alternat		J. G.		oduction?	
	(mm/dd/yyyy)			#2				#1 V Y	es No	Does
Life-threate	-	Congenital Anomaly/E ✓ Other Serious (Import)		6. Lot	#	7. Expiration	n Date	#2 TY	es No	Does
		manent Impairment/Dam		#1		#1	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	9 NDC t	or Unique	Appl
				#2		#2		U. 1400 H	or oradan	
3 Date of Event		4. Date of this Report 11/21/2013	(timescary, AAAA)	E. S	USPECT MED	ICAL DEVI	CE	COLUMN TO SERVICE	ALC: WAR	RESERVE
	nt. Problem or Product			Principal Control	nd Name		The same of the same			
I recently	switched from	rigerattes to the								
		topped smoking th		2 Con	nmon Device Nam	10				
symptoms.	I was concerned	about my breath	constantly			or the state				
		ects of an anxiet topped smoking it		2.55						
	some effects.	composition of	41.4 2 30222	3. Mar	ufacturer Name, C	City and State				
				LIAT.						
				4. Mod	(a) #	Lot#			E Onesata	s of Davis
				4. MOC	161 #	Lot **			5. Operato	
										FICHCESIOI
				Cata	alog#	Expiration	on Date (mr	n/dd/yyyy)	Lay Us	er/Patient
									Other	
6 Relevant Test	s/Laboratory Data, Incl	uding Dates		Seri	al#	Other#				
				6. If In	planted, Give Dat	e (mm/dd/yyyy)	7. If Ex	planted, Gi	ive Date (m	m/dd/yyyy
					nis a Single-use De Yes ∏ No	evice that was	Reprocess	ed and Rei	used on a F	atient?
					s to Item No. 8, Ent	ter Name and Ac	idress of Re	processor		
7 046 2 1	Atlinton, to built - 7	aulatina Madinat On 1919								
allergies, race,	pregnancy, smoking and	existing Medical Conditi I alcohol use, liver/kidney	problems, etc.)							
Race: White	2			F. 0	THER (CONC	MITANT)	IEDICAL	PRODU	стѕ	
	and a second comment of the second of the second of the second of	olood pressure/ h	igh	Produ	ct names and ther	apy dates (exc	lude treatme	ent of event	)	
chloestro.	Te									
Allergies	: none									
Important	Information:		O	G. R	EPORTER (See	e confidenti:	ality secti	on on ba	ick)	
			74.7	1. Nan	ne and Address		., 5550			
	FAVAILABILITY le for Evaluation? (Do n	of early product to EDE	A CONTRACTOR OF THE PARTY OF TH	11	ne: <b>(b)</b> (6)					
				Add	ress.					
Yes N	Returned to Ma	mulacturer on: (m	m/dd/yyyy)							
	PRODUCT(S)	A SE SECTION	BEEL BURG	Phone				le: ZIF	US	1
	h, Manufacturer (from p e rhino e cig li			(b) (6			E-mail			
Strength: 25		quia		(~) (						
	white rhino			1	Ith Professional?	3. Occupation		4.	Also Repo	
#2 Name:	said i				Yes No				Manufa	
Strength:					u do NOT want you				User Fa	
Manufacturer:						ace an "X" in thi			Dantaster	tor/Import

Internet Consumer Report

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

Triage unit sequence #

## MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

See OMB statement on reverse

A. PATIENT IN	FORMATION	不要 5年 年	OR ALLEGO	2. D	lose or Amount	Fraque	ncy Route	1745-1-124
Patient Identifier	2. Age at Time of Event or	3. Sex	4. Weight	#1		<u> </u>		111111111111111111111111111111111111111
b) (6)	Date of Birth: 57 Years	▼ Female	200 lb					
	(b) (6)	☐ Male	or .	#2 [				
In confidence			kg kg					
	EVENT, PRODUCT PR	OBLEM OR E	RROR	3. Date	es of Use (If unknow best estimate)	n, give duration		nt Abated After Use of or Dose Reduced?
heck all that apply:  Adverse Event	Product Problem (e.	a defects/malfun	clions	#1				Yes No Doe
No. County	rror Problem with Differ	- <del></del>		#2				App
	uted to Adverse Event			4 Dia	gnosis or Reason fo	r Use (Indicati	on)	Yes No Doe
(Check all that app				#1				t Reappeared After troduction?
Death:	mm/dd/vyvvi) ☑ ☑ Disa	ability or Permanent	t Damage	#2				Yes No Doe
Life-threatening		genital Anomaly/Bi						Ves ONo ODO
	- initial or prolonged  Othe			6. Lot	#	7. Expiration	Date	Apr
Required Interv	vention to Prevent Permanent	Impairment/Damaç	je (Devices)				9. NDC	# or Unique ID
Date of Event (mi		te of this Report (	rnm/dd/yyyy)	#2	1100505	#2		
11/23/2013		/25/2013		100000	USPECT MEDI	CAL DEVIC	<b>FIGURE</b>	medical like
	Problem or Product Use Erro has started using e		n our	1. Bra	nd Name			
office. I ge	t headaches and a s	ore throat w	hen she		#11 1 J 1 1 1	31 171/4	013 00 1 00	
	eek, I developed br ealthcare worker as			2. Con	nmon Device Name			4 - 11/2
(I have neve		44 A Ball	are now to W.A. s					
			and the field	3. Mar	ufacturer Name, Cit	y and State		
			4.45					for all the same
			1					
				4 Mod	lel#	Lot#		5. Operator of Dev
								Health Profession
				Cata	alog #	Expiration	n Date (mm/dd/yyyy	Lay User/Patien
								Other
Relevant Tests/La	boratory Data, Including Da	ites		Seri	al#	Other#		Ciner:
				301		Other w		N 10 10 10 10 10 10 10 10 10 10 10 10 10
				0.161	1-1-1-5/	(1)	In item 1	
				6. If Im	planted, Give Date	(mm/ad/yyyy)	/ If Explanted, C	Give Date (mm/dd/yyy
				8. Is th	is a Single-use Dev	ice that was R	eprocessed and Re	eused on a Patient?
					Yes No			HICA III
			1 - 6 4 - 1	9. If Ye	s to Item No. 8, Enter	Name and Add	iress of Reprocesso	r
Other Relevant Hi	story, Including Preexisting gnancy, smoking and alcohol	Medical Conditio	ns (e.g.					
Race: White	greency, stricturing and arconor	use, iivei/kiuney pi	Guarris, etc.)	E 0	THER (CONCO	AIT A NIT L BAS	EDICAL PRODU	ICTS
Medical Como	litions: bronchitis		10-11-60	-	t names and therap		THE RESERVE AND DESCRIPTION OF THE PERSON NAMED IN	
						,		1 11 71 1
Allergies: (	possibly) tetracycl	ine						
Important In	formation:		pre-	1				ald page
				And the Party of t	EPORTER (See	confidential	ity section on b	ack)
C. PRODUCT A		AND THE		Nam Nam	e and Address (b)	(6)		
Product Available fo	or Evaluation? (Do not send p	product to FDA)		Add	73 3 7 6 60 3			
Yes No	Returned to Manufacture	on:	14					
D. SUSPECT PI	RODUCT(S)	(mm	Vdd/yyyy)	City:	(b) (6)		State (b) Z	P. (b) (6)
AT THE PLANT AND ADDRESS OF THE PARTY.	lanufacturer (from product la	bel)		Phone	#		E-mail	, , , , ,
		7			(b) (6)			(b) (6)
Name, Strength, Name: ecigare				1				
Name, Strength, Name: ecigare Strength:				2 Mari	th Professional?	Occupation		Also Reported to
Name, Strength, Name: ecigare Strength: Manufacturer:					th Professional? 3	. Occupation	4	Also Reported to:
Name, Strength, N 1 Name: ecigare Strength:					th Professional? 3 Yes No u do NOT want your i			Also Reported to:  Manufacturer  User Facility

The FDA Safety Information and

For VOLUNTARY reporting of adverse events, product problems and product use errors 1/7

FDA USE ONLY

Triage unit sequence #

1	Adverse Event I	Reporting Program		113							
	A. PATIENT IN	FORMATION	ALMERICA ST	10 THE ST.	2 D	lose or Amount	Freque	ncy Ro	ute		
		2. Age at Time of Event of	F 3. Sex	4. Weight	#1 7	nicotine	As nee	ral	ken by	/ mouth	
(	b)	Date of Birth: 46 Years	☐ Female	250 <sub>lb</sub>	II L						
		(b) (6)	(Z)	10	#2						
- 1	In confidence	(=)(=)	✓ Male	kg							
1	B. ADVERSE	EVENT, PRODUCT P	ROBLEM OR EF	RROR		es of Use (If unknown, best estimate)	, give duration,			Abated Afte	
- 1	Check all that apply:	_		3		/04/2013 - 12/1	12/2013			es No	Doesn't
	1. Adverse Even	- Longe			#2					es (4) 140	Apply
		rror Problem with Diff	erent Manufacturer o	of Same Medicine			Han Undantin	#2	2 🗌 Y	es No	Doesn't
	<ol><li>Outcomes Attribe (Check all that app</li></ol>	uted to Adverse Event				gnosis or Reason for licotine addiction				Reappeared	d After
- 1	Death:	-	isability or Permanent	Damage						roduction?	C D
	✓ Life-threatening	mm/dd/yyyy)	ongenital Anomaly/Birl	Ib Defeat	#2			#	1   Y	es No	✓ Doesn't Apply
		-			6. Lot	*	7. Expiration	Date #	2 <b>T</b> Y	es No	☐ Doesn't
		- initial or prolonged One			#1	*	#1		NDC +	For Unique	Apply
1		411			#2		#2		NUC R	FOr Unique	IU.
- 1	(b) (6)		Date of this Report (n	nm/dd/yyyy)		LICECT MEDIC				-	
-	35.07.07		2/21/2013		The second	USPECT MEDIC	AL DEVICE	=		100	
-1		Problem or Product Use E ng my e-cigarette,		Ottenne	I, brai	(C) IVAIIIY					
		afire protected 1.									
		a Joytech pro 2 th			2. Соп	nmon Device Name					
X		the battery which protect from this									
BLACK INK	outgass and	explode. It ignite	ed the gas and	exploded	3. Man	ufacturer Name, City	and State		-		Many and Arrivant
AC.		upper denture, bro									
35.		ushed to the count									
		1st and 2nd degree			4 Mod	iel#	Lot#			5. Operator	of Device
TYPE OR USE		y spetum tore three loss and possible		cavity							rofessional
K											
E				to the second	Cata	slog #	Expiration	Date (mm/do	(עעעעיב	Lay Use	r/Patient
FI				, 144						Other:	
SET	6. Relevant Tests/Li	aboratory Data, Including	Dates		Seri	al#	Other #				
AS				, A							
PLEA					6. if im	planted, Give Date (i	mm/dd/vvvv)	7. If Explan	nted, Gi	lve Date (mr	n/dd/vvvv)
4						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			, .		
1			TU		and the second second	is a Single-use Devi	ce that was R	eprocessed a	and Rea	used on a P	atient?
						Yes No					
		ner	2 3 2013		9. 17 70	s to Item No. 8, Enter i	Name and Add	ress of Repro	Cessor		
	7. Other Relevant H	istory, including Preexisti	ng Medical Condition	ns (e.g.,							
	Race: White	gnancy, smoking and alcoh	or use, liver/klaney pri	oolems, etc.)	E 0			DIO LL DE	30011	070	
						THER (CONCOM					
		ditions: SLE, psor s, and interstitia			Produc	ct names and therap	y dates (exclu	de treatment d	of event	D)	
		tuitary tumor, h									
- 1	hypogonadism	n,									
	Allergies: 0	Comtrast dye, perc	ocet, betadyne,	, imodium,	G. RE	EPORTER (See c	onfidential	ity section	on ba	ack)	11-22-1
- L					1. Nam	e and Address		,		,	
- 2	C. PRODUCT A	The state of the s		A FELDERAL SERVICE	Nam	ne: (b) (6)					
		or Evaluation? (Do not sen			Addi	ress:(b) (6)	THE ST				
	Yes No	Returned to Manufact		(dd/yyyy)		(1.1 (0))		11			
	D. SUSPECT PI	RODUCT(S)	Water Street St.	BEN SERVICE AND ADDRESS OF THE PERSON NAMED IN COLUMN 1		(b) (6)		State	D) ZIF	): (b)	
12	The state of the s	danufacturer (from produc	t label)		Phone			E-mail			
(	Name: smok				(b) (6	)		(b) (6)		SERVICE PROPERTY.	
1	Strength: Manufacturer: sm	nok cigarette			2. Heal	th Professional? 3.	Occupation		14.	Also Repor	ted to:
2		ion cryaterie				Yes No				Manufac	
1"									1		
	2 Name: Strength:				5 If vo	u do NOT want your ic	ientity disclose	ed		User Fa	cility

#### 8.5. Describe Event or Problem (continued)

... necrosis. I have been adicicted to chewing tobacco for 10+ years and my pulmonologist recommended I try an ecigarette afte the patch, lozenges and nicotine gum failed. I suffer from SLE, psoriatic arthritis, osteoporosis, and interstitial lung desease that took my left lung last year. Hydromorphone 4mg as well as several salves have been prescribed. Im 46 male contact (b) (6)

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

... snus use for 10 + years

RX Meds: Oxygen and 4 liters, prednisone, vitamin d3, calcium, reclast, newvigil, Hydromorphone, arava, imuran, gliperide, bupivicane, pristiq, wellbutrin, xanax,

OTC Meds:

Marke 1

80 -

U.S. Department of Health and Human Services

Internet Consumer Report

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

# **MEDWATCH**

For VOLUNTARY reporting of adverse events, product problems and

FDA USE ONLY

Triage unit

	The FDA Safety Informa Adverse Event Reporting	E115 N1 (E1 C TC		product us	gerro	rs	sequer	ice#		
	A. PATIENT INFORMA	TION	A 181		2.	Dose or Amount		requency	Route	
	1. Patient Identifier 2. Age at 1		3. Sex	4. Weight	#1	Dose of Amount	——	requency	Kodu	
	(b) (6) Date of		J. GEX	L. C.A. SELECTION OF CO.					11	111
	32 Year	rs	Female	180 <sub>lb</sub>					_	
	The state of the s	(b) (6)	✓ Male	Of .	#2					
	In confidence		Male	kg kg						
	B. ADVERSE EVENT, F	PRODUCT PRO	BLEM OR EF	RROR	3. Da	tes of Use (If unkno	wn, give du	uration) from		t Abated After Use
	Check all that apply:				. (01	best estimate)			Stoppe	d or Dose Reduced?
	C. (1907)1	oduct Problem (e.g	defects/mailtunc	tions)	#1 1	month			#1 2	Yes No Doesn't
	Product Use Error Pro	AND A THE PARTY OF		. 65	#2					Apply
			Hemanulacion (	A Sellie Medicille	A Die	gnosis or Reason	Kantilan (In	offention)	#2 []	Yes No Doesn't
	<ol><li>Outcomes Attributed to Adv (Check all that apply)</li></ol>	verse Event		1 409		Micotine withdr		iorçauori)	8 Even	t Reappeared After
1		(T)				MICOCING WITHUI	awal.		Reini	troduction?
	Death:		ility or Parmanent	Damage	#2				—  #1 []·	res No Doesn't
	Life-threatening		enital Anomaly/Bir	th Defect	72					Apply
					6. Lo	• #	7 Evol	iration Date	#2 🗍	Yes No Doesn't
	Hospitalization - initial or p				1000	BC (Batch #)	#1	Heron Date		Apply
1	Required Intervention to P	revent Permanent I	mpairment/Damag	e (Devices)		DE (BRECH #)			9. NDC	# or Unique ID
	3. Date of Event (mm/dd/yyyy)	4. Date	of this Report (n	mm/dd/yyyy)	#2		#2			
	12/23/2013		24/2013		E.	SUSPECT MED	ICAL DE	VICE	STORY OF ST	DATE OF STREET
	5. Describe Event. Problem or				The same of	nd Name				
	5. Describe Event, Problem or Back in early Novem									
ı	cigarette and felt							ü.		
	Later in the day, I				2 Co	mmon Device Nam				
1	could not breathe.						7			
Z	situation could have	e been extrem	nely dangerou	is for	1					
Z	myself and patients				3 Ma	nufacturer Name, C	ity and St	ate		
BLACK	for years and just									
اک	cigarettes around O				1		-	141		
	printed ingredients other products I've				1	6				
OSE	their product again				4. Mo	del#	Lot	#		5. Operator of Device
D	the same reaction.									Health Professional
8				1						
E					Car	talog #	Ехр	Iration Date	(mm/dd/yyyy)	Lay User/Patient
2							1			
										Other:
u	6 Relevant Tests/Laboratory I	Data, Including Da	ETU	8.1	Sei	rial#	Othe	er#		
2										
Ή		DEC	A 4 2040	3.04						
뢰		DEC	26 2013	1 1	6. If Ir	mplanted, Give Date	mm/dd/y	γγγ) 7. <b>f</b> f	Explanted, G	live Date (mm/dd/yyyy)
- 1										
- 1				9-			vice that	was Reproce	essed and Re	used on a Patient?
-				1	-	Yes No				
-1				- 1	9. HY	es to Item No. 8, Entr	er Name an	d Address o	f Reprocessor	
ł	7. Other Relevant History, Incl.	uding Droovleting I	Hadisal Candition	20 /0 0	1					
	allergies, race, pregnancy, sm	alilan and alsohal .	an time Addance on	ablama atal	1					
	Race: White				E 6	THER (CONCO	BAITANE	MEDIC	AL DROD	ICTS
	Medical Conditions:	None		1	Produ	ict names and there	py dates	exclude trea	arment of even	r)
	Allergies: Sulfa			1						
	arrerates: Sulla				1					
	Important Information	on:			1					
				13	G. R	EPORTER (See	confide	entiality se	ection on b	ack)
				12/4		ne and Address		, 00		The state of the s
	C. PRODUCT AVAILABI	LITY			Nar	A. v	(6)			
	Product Available for Evaluation	on? (Do not send pr	roduct to FDA)				(6)			* -
1	Yes No Return	ned to Manufacturer		1	1	(-	1 4-1			
	Yes No Return	ing to interioracional	(mm/	od/yyyy)		Oh COV				
1	D. SUSPECT PRODUCT	(S)		(150 T 5 3 S	City	<b>(b)</b> (6)			State: ZII	P: (b)
	1. Name, Strength, Manufacture		el)		Phone			E-m	ail	100
	#1 Name: Nicotine Cartr				11-19	(b) (6)		4	1	(b) (6)
	Strength: 18mg and 24mg				The state of the s				THE RESERVE TO SERVE THE PARTY OF THE PARTY	
1	Manufacturer: V2 Cigs w		1		2. Hea	Ith Professional?	3. Occupa	tion	4	Also Reported to:
1	THE PERSON NAMED IN COLUMN TWO IS NOT THE PERSON NAMED IN COLUMN TWO IS NAMED IN COLUMN TW	+20193.001				Yes No		100 A (0.00)	1.	Manufacturer
1	Name:			2.77						
1	Strength:			1 2		ou do NOT want you			F2	User Facility
1	Manufacturer:				to t	he manufacturer, pla	ce an "X" i	n this box:	LZ	Distributor/Importer

#### B.5. Describe Event or Problem (continued)

... regarding the incident and they refused a refund and to take them back. I contacted them again stating that there was a problem with their product and they needed to take it back due to a serious reaction that occurred. I again spoke with a representative on 12-23-13 and told them that I was more disturbed that they did not want to take the product back to see what might be wrong and the individual after speaking with a supervisor stated that they would take them back. After going back online to print a label to return the product to them, I saw that they sent me a notice and they were again refusing to take their product back. This was a \$50 order and I am not concerned about the money. I think something seriously wrong is going on with this company because once again, I have not had a problem with any of their printed ingredients in regards to electronic cigarettes from other company's in the past. Their nicotine liquid is manufactured in China.



From: Sent: Wednesday, December 25, 2013 9:21 PM

To: OC Ombudsman

Subject: Contaminated Product

I ordered 60 ml of a vegetable glycerin and nicotine mixture(not labeled USP) for use in a smoking cessation product. The product I received was contaminated with a machine oil or grease. I wrote an email to the company explaining that the product smelled and tasted like machine oil. Vegetable glycerin is odorless while nicotine is relatively odorless but may have a slight chemical smell. The response I received was offensive and suggested that I was to blame or I was mistaken, but they offered to send a replacement after I performed a series of tests to assure them it was not my fault. I responded, clearly explaining that it was their product that was the problem and told them that response I received was offensive and unintelligent. Because I suspect the residue was inside the bottle in which the product was contained, which is a common occurrence when using new, low-quality bottles. The company then ignored any future emails I sent and gave no refund or replacement. Because of using this product, I have suffered nausea, diarrhea, nose-bleeds, sore throat, dizziness, shortness of

breath, and fatigue.



non-responsive	THE RESERVE OF THE PERSON NAMED IN	THE RESERVE OF THE PARTY OF THE
SE SALES METHODS		
SERVICE STREET, STREET		
<b>发生以外,但是一个人的</b>		
Windles and Market		

From:

Sent: Tuesday, November 12, 2013 9:40 AM

To: Chang, Nancy

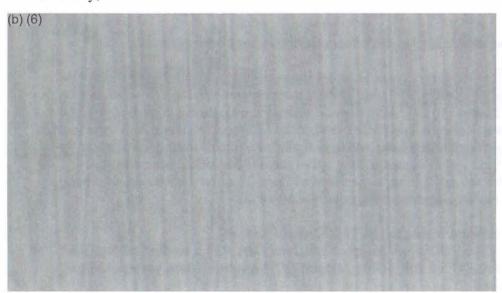
Subject: Fwd: Incident 11-13-012 involving an electronic cigarette

Ms. Chang,

I am forwarding this information from the (b) (6) . This incident recently occurred in our jurisdiction and I plan on issuing a news release concerning this problem. I spoke with my friends at (b) (6) and they directed me to you regarding this serious issue. Does the FDA have any additional details that I can use in my safety release relating to this issue? Is the link on the email valid and/or is there a better link to refer to the public concerning this hazard?

Please see below.

Sincerely,



From: (b) (6)

Date: Tue, Nov 12, 2013 at 8:55 AM

Subject: Fwd: Incident 11-13-012 involving an electronic cigarette

To: (b) (6)

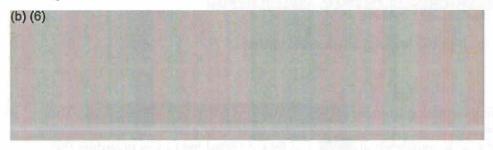
Cc: "(b) (6)

Bruce,

I spoke with (b) (6) about this Friday and he and I thought it might be a good topic for a statewide prevention release. This reminded me of the news link you sent a month or two ago about the e-cigarette that blew up and burned the child in the car seat. Here is a link to a recall on the batteries as well.

http://www.e-cigarette-forum.com/forum/general-e-smoking-discussion/444286-evod-battery-recall.html

Regards,



----- Forwarded message -----

From: (b) (6)

Date: Tue, Nov 5, 2013 at 3:02 PM

Subject: Incident 11-13-012 involving an electronic cigarette

To: (b) (6)

(b) (6)

On Sunday, November 03, 2013 at 1030 hours the following events occurred:

(b) (6) is on home oxygen at his residence at (b) (6)
(b) (6) wife (b) (6) is taking care of him. They both smoke cigarettes. Since October 09, 2013 they have been using the electronic cigarettes. (b) (6) plugged an electronic cigarette into the usb port of the computer to charge it..as time went by (not sure how long) they heard a bang and then smoke and flames coming from under (b) (6) hospital bed. The E- cigarette blew out of the usb port of the computer and exploded hitting the bed and falling to the carpeted floor. The fire was extinguished using water by (b) (6) No fire department response and no injuries.

I investigated the incident further today. This is what I learned. The E- cigarettes: Type EVOD (no model or serial number) with a combo style wall/usb charger of eGo input: DC 5.0 volt, 500ma, output: DC 4.2 volts, 420ma. purchased from Vapor Hut in Oakland.

The batteries exploded during charging shooting the battery with end cap to the bed and landing on floor. The battery is in my professional opinion are similar to a wrist watch style battery.

Vapor Hut could not provide any type of model number or UL number for the EVOD style cigarette.

They showed me a battery that is a little smaller in diameter than a AAA battery. I suspect that this battery has several wrist watch style batteries joined in series and packed with a plastic wrap.

Vapor purchases these EVOD cigarettes online from <u>vivian@bilsencig.com</u>. The cigarettes are manufactured in ShenZhen, China.

I photographed the incident and advised the (b) (6) to contact there insurance company.

Property damage is estimated at 500.00 dollars.

Regards,





Internet Consumer Report

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

FDA USE ONLY

Triage unit sequence #

The FDA Safety Information and

For VOLUNTARY reporting of adverse events, product problems and

A PATIENTIN	FORMATION.		THE RESERVE OF THE PERSON NAMED IN	I .		Annual Control of the	
Patient Identifies	IFORMATION	nt or   3. Sex	4. Weight	2. Dose or Amous	nt Freque	ncy Route	
(b) (6)	Age at Time of Ever     Date of Birth:	iicor S. Sex	185 <sub>lb</sub>				
	65 Years	Female	lb	#2			
	(b) (6)	✓ Male	or kg	72			
in confidence	EVENT PRODUCT	T PROBLEM OR E		3 Dates of Lies Of u	known give duration	\frac{1}{2} \frac\	t Abated After Use
heck all that apply:	EVERT, PRODUC	PROBLEMORE	RROR	(or best estimate)	aniown, give databoli		or Dose Reduced?
. Adverse Event	t Product Probl	em (e.g., defects/maifund	ctions)	#1		#1 🔲 ነ	es No Does
		Different Manufacturer	Manage and	#2			Apply
	uted to Adverse Event			4. Diagnosis or Rea	son for Use (Indication	#2 \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	es No Does
(Check all that app			and I	#1	and training		Reappeared After
Death:		Disability or Permanent	t Damage				roduction?  'es No Does
Life-threatening	mm/dd/yy <sub>?</sub> y)	Congenital Anomaly/Bl	rth Defect	#2		#1	Apph
	-	Other Serious (Importar		6. Lot #	7. Expiration	Date #2	es No Does
		anent Impairment/Damag		#1	#1		# or Unique ID
			4.5	#2	#2	3. 1400	or ornique to
Date of Event (mr	macryyyy)	4. Date of this Report (	mm/dd/yyyy)	E CUEDECT N			
01/04/2014		01/05/2014	47 . 34.3.	1. Brand Name	EDICAL DEVIC	Control of the Control	1000
	Problem or Product Us	se Error ce he has been i	n the	1. DIGITO NATITE			
		g a e cigarette.					
after about	30 minutes to a	hour of exposur	9	2. Common Device	Vame		
		experienced diffi He did not have					
		after leaving i			80 101		
put on oxyge	en. He continued	to have difficu		3. Manufacturer Nan	ne, City and State		
breathing ti	11 the following	g day.		188 387 13			
							*
			K H XII - U	4. Model #	Lot#		5. Operator of Devic
				1333			Health Profession
				Catalog #	Expiration	Date (mm/dd/yyyy)	Lay User/Patient
			THE PARTY NAMED IN		a.p.i.udoi		
D.L		ti - Data					Other;
Relevant Tests/La	aboratory Data, Includi	ing Dates		Serial #	Other#		
	CIL	y		6. if Implanted, Give	Date (mm/dd/vvvv)	7. If Explanted. G	ive Date (mm/dd/yyyy,
			1				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
		2014		8. Is this a Single-us	e Device that was R	eprocessed and Re	used on a Patient?
	JAN -7			- mm			
	JAN -7	EUN		Yes No			
	JAN -7	E014	Fig. 5	Yes No	Enter Name and Add	ress of Reprocessor	
Other Relevant Hi	istory, Including Preex	cisting Medical Conditio	19 E 5		Enter Name and Add	ress of Reprocessor	
allergies, race, pre-	istory, Including Preex		ins (e.g., roblems, etc.)	9. If Yes to Item No. 8.			
Other Relevant Hi allergies, race, pre- Race: White	istory, Including Preex	cisting Medical Conditio	ins (e.g., roblems, etc.)				
allergies, race, pres Race: White	istory, Including Preex	cisting Medical Conditio	ins (e.g., roblems, etc.)	9. If Yes to Item No. 8.	(COMITANT) ME	EDICAL PRODU	стѕ
Allergies, race, pre- Eace: White Medical Cond	istory, Including Preex grancy, smoking and al ditions: COPD	cisting Medical Conditio	ins (e.g., roblems, etc.)	9. If Yes to Item No. 8.	(COMITANT) ME	EDICAL PRODU	CTS
Allergies, race, pres Race: White	istory, Including Preex grancy, smoking and al ditions: COPD	cisting Medical Conditio	ins (e.g., roblems, etc.)	9. If Yes to Item No. 8.	(COMITANT) ME	EDICAL PRODU	CTS
Allergies: n	istory, Including Preex grancy, smoking and al ditions: COPD	kisting Medical Conditio Icohol use, liver/kidney pi	roblems, etc )	9, If Yes to Item No. 8  5. OTHER (CON Froduct names and	(COMITANT) ME therapy dates (exclu	EDICAL PRODU de treatment of even	ICTS
Allergies: nace.pre	istory, Including Preex egnancy, smoking and al ditions: COPD	kisting Medical Conditio Icohol use, liver/kidney pi	ons (e.g., roblems, etc.)	5. OTHER (CON Froduct names and	ICOMITANT) ME therapy dates (exclu	EDICAL PRODU de treatment of even	ICTS
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allergies, race, presace: White  Medical Cond  Allergies: n  Important In  PRODUCT A	istory, Including Preex Including Including Preex Including Including Inclu	risting Medical Condition location use, liver/Rudney pure lead in the past send product to FDA)	roblems, etc )	5. OTHER (CON Froduct names and  G. REPORTER (1. Name and Address	(COMITANT) ME therapy dates (exclu 'See confidential s	EDICAL PRODU de treatment of even ity section on ba	ICTS
Allergies: name present allergies: name allerg	istory, including Preex sgnancy, smoking and all ditions: COPD none nformation: smok	risting Medical Condition looked use, liver/Rudney put the looked in the past send product to FDA) facturer on:	roblems, etc )	G. REPORTER (In Name and Address)	(COMITANT) ME therapy dates (exclu (See confidential s 5) (6)	EDICAL PRODU de treatment of even ity section on ba	ICTS I) ack)
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Allergies: name. pre. Race: White Medical Cond Allergies: name. Important In PRODUCT A Product Available for Yes No. SUSPECT P. Name, Strength, No.	istory, Including Preex signancy, smoking and all ditions: COPD none nformation: smok  VAILABILITY or Evaluation? (Do not) Returned to Manual  RODUCT(S) Wanufacturer (from proc	risting Medical Condition looked use, liver/fudney put the past send product to FDA) facturer on:	roblems, etc.)	G. REPORTER  1. Name and Address Name: Address: City: (b) (6) Phone #	(COMITANT) ME therapy dates (exclu (See confidential s 5) (6)	EDICAL PRODU de treatment of even ity section on ba (6) State: (b) ZIF	ack)
Allergies, race, present allergies; name, Strength, Wallander e cigar	istory, Including Preex signancy, smoking and all ditions: COPD none nformation: smok  VAILABILITY or Evaluation? (Do not) Returned to Manual  RODUCT(S) Wanufacturer (from proc	risting Medical Condition looked use, liver/fudney put the past send product to FDA) facturer on:	roblems, etc.)	9. If Yes to Item No. 8  5. OTHER (CON Froduct names and  G. REPORTER  1. Name and Address Name Address:  City: (b) (6)	(COMITANT) ME therapy dates (exclu (See confidential s 5) (6)	EDICAL PRODU de treatment of even ity section on ba (6) State: (b) ZIF	octs  ack)
Allergies, race, presented in the Medical Condition of the Medical Cond	istory, Including Preex signancy, smoking and all ditions: COPD none nformation: smok  VAILABILITY or Evaluation? (Do not) Returned to Manual  RODUCT(S) Wanufacturer (from proc	risting Medical Condition looked use, liver/fudney put the past send product to FDA) facturer on:	roblems, etc.)	G. REPORTER  1. Name and Address Name: Address: City: (b) (6) Phone #	(COMITANT) ME therapy dates (exclu See confidential s b) (6)	EDICAL PRODU de treatment of even ity section on ba (6) State: (b) ZIR E-mail	(b)
Allergies, race, present allergies; medical Cond Allergies: m Important In PRODUCT A roduct Available for Yes No SUSPECT PE Name, Strength, N Name e cigar Strength: Manufacturer:	istory, Including Preex signancy, smoking and all ditions: COPD none nformation: smok  VAILABILITY or Evaluation? (Do not) Returned to Manual  RODUCT(S) Wanufacturer (from proc	risting Medical Condition looked use, liver/fudney put the past send product to FDA) facturer on:	roblems, etc.)	6. REPORTER 1. Name and Address Name Address: City: (b) (6) Phone # (b) (6)	(COMITANT) ME therapy dates (exclu See confidential s b) (6)	EDICAL PRODU de treatment of even ity section on ba (6) State: (b) ZIR E-mail	ach)  (b) (6)  Also Reported to:
allergies, race, presace: White Medical Cond Allergies: n Important In Product Available for Yes No SUSPECT PR Name, Strength, W Name a cigar Strength:	istory, Including Preex signancy, smoking and all ditions: COPD none nformation: smok  VAILABILITY or Evaluation? (Do not) Returned to Manual  RODUCT(S) Wanufacturer (from proc	risting Medical Condition looked use, liver/fudney put the past send product to FDA) facturer on:	roblems, etc.)	G. REPORTER  1. Name and Address Name: Address: City: (b) (6) Phone #	(COMITANT) Me therapy dates (exclusive confidential section (b) (b)	ity section on back  State: (b) Zif  E-mail (b)	(b) (6)

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.





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

For VOLUNTARY reporting of adverse events, product problems and

FDA USE ONLY

	TAICH			problems and		ge unit uence #	oln d	
	/ Information and Reporting Program	pro	odtičť tise (	Frors	V			
A. PATIENT I	NFORMATION	SPORTS AND PR	Commence of the Commence of th	2. Dose or Amou	int	Frequen	cy Route	3
1 Patient Identifier	2. Age at Time of Event or	3. Sex 4. Wei		#1				
(b)	Date of Birth:	▼ Female	120 <sub>lb</sub>					
1	26 Years (b) (6)			#2				
In confidence	(6) (6)	Male or	kg					
	EVENT. PRODUCT PR	OBLEM OR FRROR		3. Dates of Use (If L	unknown, give	duration)	from/to 5 E	vent Abated After Use
Check all that apply:			and a comme	(or best estimate)				oped or Dose Reduced?
1. Adverse Ever	nt Product Problem (e	g . defects/malfunctions)	#	in			#1 {	Yes No Doesn
	Error Problem with Differe		Medicine	12			-	
2 Outcomes Attrib	outed to Adverse Event			. Diagnosis or Res	ason for Use	(Indication	#2 [	Yes No Doesn
(Check all that ap			- 11	#1				vent Reappeared After
Death:		bility or Permanent Damage						eintroduction?  Yes No Doesn
Life-threatenin	(mm/dd/yyyy)	genital Anomaly/Birth Defect	. 11	#2			#1 [	Apply
				5. Lot#	7 E	xpiration (	79to #2 [	Yes No Doesn
	n - Initial or prolonged Other		- 1	#1	#1	April audit i	, , ,	Apply
Required Inter	rvention to Pravent Permanent	impairment/Damage (Devic	-	#2			9 N	DC # or Unique ID
3 Date of Event (n		e of this Report (mm/dd/yy	(7/7)		#2			
12/09/2013	02/	07/2014	l po	E. SUSPECT	MEDICAL	DEVICE	THE THE PARTY	A TRUE ST
	Problem or Product Use Erro			Brand Name E-cigarette/	/haaksh			
	red burning eyes af		sed	L-Cigarette/	nookan			
	omeone smoking an e- more than one occas			2. Cámmon Device	Name			
	ple with the same bu	rning feeling in t	heir	E-cigarette/				
eyes.			Mill II	15				
4			3	. Manufacturer Na		State		
3			, Lea	Nemesis, RSS	ST			
			15 300					
several peo eyes.				Model #	TL	ot#		5. Operator of Device
5			2.2					Health Professional
1			20	L. L.				
				Catalog #	E	xpiration l	Date (mm/dd/y)	(1/1/2) Lay User/Patient
			1					Other:
6. Relevant Tests/L	aboratory Data, Including Da	tes		Serial#	0	ther#		
			6	8. If Implanted, Give	e Date (mm/d	(d/yyyy)	7 If Explanted	d, Give Date (mm/dd/yyyy)
				In this a Otania	no Davidos di	nt wan fi		Daymad ca a Cattana
				Yes No	ea navice (U	at was Ke	nocessed and	Reused on a Patient?
			1	), if Yes to Item No. 8	8. Enter Name	and Addre	ss of Reproces	seor
				.,	-,			
	listory, Including Preexisting		0(0.)					
Race: White	egnancy, smoking and alcohol	use, livel/kiditey problems, t		ATUEN (00)	NACHITA			211222
			l per	OTHER (CO		- 100		
Medical Con	ditions:			Product names and	therapy dat	es (exclude	reatment of e	ven:)
	Allergic to peanut b	utter (only within	the					
last year),	pollen, trees, I ta							
this			3 H 7		10			
			100000	REPORTER		dentialit	y section or	n back)
C. PRODUCT	AVAILABILITY	EST STATE OF LAND		Name and Address		7/8		
	for Evaluation? (Do not send p	product to FDA)	100	Address:	(b) (6	7		
TYes No	Returned to Manufacture	4	2760					
	Thermied to Manningcine	(mm/da/yyyy)						
D. SUSPECT P	PRODUCT(S)			City:			State:	ZIP:
1 Name, Strength,	Manufacturer (from product la	bel)	F	hone #			E-mail	
#1 Name								(b) (6)
Strength:				Lleath Cartessia	nol2 2 De	unation.		4 Also Personal to
Manufacturer			2	. Health Profession	Half 3. UCCI	pation		4. Also Reported to:
#2 Name				Yes No				Manufacturer
Strength:			15	i. If you do NOT wan				User Facility
Manufacturer:			1	to the manufacture	er, place an ")	A IN INIS D	ox: 🗸	Distributor/Importer

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

... Disorder, Celexa for Depression

OTC Meds: Zyrtec (nightly for allergies), Emergen-c vitamin packet, Vitamin D3, Melatonin for sleep



U.S. Department of Health and Human Services

Internet Health Professional Report

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

The FDA Safety Information and

For VOLUNTARY reporting of adverse events, product problems and product the errors FDA USE ONLY

Triage unit sequence #

	Adverse Event F	Reporting Program								
1	A. PATIENT IN	FORMATION	STATE OF THE	ALC: YELLOW	2	Dose or Amount		Frequency	Route	
		2. Age at Time of Event or	3. Sex	4. Weight	, #1				Respira	torv
	(b) (6)	Date of Birth:			13				li cospii a	
	(0)(0)	0	✓ Female	Ib Ib	#2		==		=	
			Male Male	or kg	72					
	In confidence				-					
		EVENT, PRODUCT PE	OBLEM OR EL	ROR	3. Da	tes of Use (if unkno best estimate)	wn, give	duration) fro		Abated After Use or Dose Reduced?
	Check all that apply:				#1					es No Doesn't
-	1. Adverse Event		•		#2					Apply
	Product Use E	rror Problem with Diffe	rent Manufacturer o	f Same Medicine			d 11	(00) 010	#2 Y	es No Doesn't
	2. Outcomes Attribu (Check all that app	ated to Adverse Event			#1	agnosis or Reason	TOF USE	(moication)	8 Event	Reappeared After
	Death:		ability or Permanent	Damana						roduction?
		mm/dd/yyyy)	2000 - Control -		#2				#1 Y	es No Doesn't
	Life-threatening	· · · · · · · · · · · · · · · · · · ·	ngenital Anomaly/Bir	CONTRACTOR OF THE PROPERTY OF						P P P P P P P P P P P P P P P P P P P
	Hospitalization	- initial or prolonged 🗸 Oth	er Serious (Importan	t Medical Events)	6. Lo			xpiration Dat	ta #2 Y	es No Doesn't
	Required Interv	vention to Prevent Permanen	t Impairment/Demag	e (Devices)		nknown	#1		9. NDC	For Unique ID
	(b) (6)	(r)d/yyy) - 4. De	ate of this Report (n	nm/dd/yyyy)	#2		#2			
	(D) (D)	01	/23/2014		E.	SUSPECT MED	DICAL	DEVICE		12 12 12 13
	5. Describe Event. P	Problem or Product Use En			1. Br	and Name				
		or of CigaWatt (12		ue						
		64014) contacted N								
ار		e event and reques			2. Co	mmon Device Nam	10			
BLACK INK	customer inh	aled the product u	sing an electi	conic 2 !	5.					
$\overline{Z}$		vice (type unknown			3) Ma	nufacturer Name,	City and	State		
3		re allergic reactive emergency room who			18.50					
Ĭ		phrine. Customer r								
		ician identify whi	A COLUMN TO A COLU		4 Me	odel#	11.	ot#		5. Operator of Device
ns		s allergic to. Ing.		ras	7. 810	AMI W	1-			Health Professional
K	provided to	vendor arong wren								neakn Protestional
0					Ca	talog#	E	xpiration Da	te (mm/dd/yyyy)	Lay User/Patient
TYPE OR USE										Other:
-	6. Relevant Tests/La	aboratory Data, Including D	Pates		80	rial#		ther#		
PLEASE	Unknown				1 30		١	with it		
EA										
7				1	6, If I	mplanted, Give Dat	te (mm/d	d/yyyy) 7	If Explanted, G	ive Date (mm/dd/yyyy)
					9 le (	this a Cinata usa F	aulca the	at was Bank	accessed and Da	used on a Patient?
						Yes No	TTIOU LIN	e, wee vabu	ANDORUG AND INS	WOOD ON B FBUOILE
						es to Item No. 8, En	ter Name	and Address	of Reprocessor	
			44 11 14						1,50	
	<ol> <li>Other Relevant His allergies, race, pre</li> </ol>	Istory, Including Preexisting gnancy, smoking and alcohole	g medical Condition Luse, liver/lidnev on	ns (e.g., oblems, etc.)						
	Unknown at t		,		F C	THER (CONC	ATIMO	NTI MEDI	CAL PRODU	ICTS
						uct names and the				
					Unkr			- Juneauw II	The same of the sa	*
					G. F	REPORTER (Se	e confi	dentiality	section on b	ack)
				of the		rne and Address			10	
	C. PRODUCT A	A CONTRACTOR OF THE PARTY OF TH		á		me: (b) (6)	LEV			
		or Evaluation? (Do not send	100	i H.	Ad	dress: (b) (6)				
	Yes No	Returned to Manufactu	rer on:	dd/yyyy)						
	D. SUSPECT PI	RODUCT(S)	THE I SHALL SEE	The same of the sa	Cit	y: (b) (6)			State: (b ZI	P: (b) (6)
1		Manufacturer (from product	label)	2	Phon				-mail	
	1 Name: Great I	AND THE RESIDENCE OF THE PARTY			(b) (	6)		(b	(6)	
	/Strength:					all Burgaria	2.0			Al D
4	Manufacturer. Ni	cVape, Inc.	*		100	alth Professional?	100	*		Also Reported to:
	V2 Name:				6.0				th Professional	Manufacturer
	Strength:					you do NOT want you				User Facility
l	Manufacturer:	(4/00)	al a mand d	Name tile de	_	the manufacturer, pl			-	Distributor/Importer
	FORM FDA 3500	J (7/U9) Submission	of a report does no	t constitute an adn	noissin	that medical person	inel or the	e product car	used or contribu	ted to the event.

#### B.5. Describe Event or Problem (continued)

... NicVape contact information for follow-up.