REPORT INFORMATION

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) 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)

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. <blank>

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

Preferred method of contact Email

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 <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

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

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)?	1.25
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?	No
Has the person had a similar health problem or product problem?	Yes
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 exposure.
What are the main symptoms or health problems? (select up to 5)	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	60

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person	(b) (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 INFORMATION

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)

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? Yes

Preferred method of contact Email

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product? No

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

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? <blank>

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 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?	No
Did the person use this product before without a problem?	No
Did the person change the product in any way before using it (for example: removing a filter from a cigarette)?	<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	Electronic cigarettes need to be regulated like normal tobacco products. The effects of second hand exposure are unknown and potentially dangerous to the public, especially children.
On average, number of pieces, pinches, dips, or rubs 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?	<blank>

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)?	4
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)	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?	No
Has the person had a similar health problem or product problem?	No
Please describe the similar health problem or product problem	<blank>
What are the main symptoms or health problems? (select up to 5)	<u>Lungs or Breathing problem</u> (such as: cough, asthma, wheezing, lung infection)

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	3
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 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	2014-01-16 14:05:09
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

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>

City/Town (b)

State (b)

ZIP/Postal Code (b)

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

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

Preferred method of contact Email

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 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? Yes

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 brand?	1
Select Unit of Measure	less than 7 days
Was the product being used when the health problem occurred?	Yes
Did the person use this product before without a problem?	No
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)?	Yes
Does the person who had the adverse event also drink alcohol?	Yes
Has the affected person used other tobacco products in the past?	Yes
How many drinks per week?	<5 drinks/week
Please describe anything else you think the FDA should know about this health problem	<blank>

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?	5
Select Unit of Measure	minute(s)
Did the person stop using the product when he/she had the health problem?	Yes
Did the symptoms from the health problem go away or get better when the person stopped or reduced the amount of product used?	Yes
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?	<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)?	3
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?	No
Has the person had a similar health problem or product problem?	No
Please describe the similar health problem or product problem	<blank>
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 None

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

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 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	2014-01-21□00:21:55
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)	(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) (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 necessary? Yes

Preferred method of contact Email

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 <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? Yes

Description of other tobacco product type e-cigarettes

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?	No
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)?	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	the use of e-cigarettes should be banned as the health effects of second hand smoke are devastating and pose inherent danger for non users.
On average, number of pieces, pinches, dips, or rubs 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?	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)?	12
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 problem:	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?	Yes
Was the person evaluated by a healthcare professional?	Yes
Date the person was first seen by a healthcare professional for this health problem	12/14/2013
Please describe any treatment the person received including results of any tests (such as x-rays, lab results, or blood work)	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 e-cigarette second hand smoke.
Has the person had a similar health problem or product problem?	No
Please describe the similar health problem or product problem	<blank>
What are the main symptoms or health problems? (select up to 5)	Burn, <u>Allergic</u> reaction, <u>Lungs or Breathing problem</u> (such as: cough, asthma, wheezing, lung infection), <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	none

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	2014-01-21 20:13:48
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)
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) (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? Yes

Preferred method of contact Email

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 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 purchased? <blank>

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 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	less than 7 days
Was the product being used when the health problem occurred?	Yes
Did the person use this product before without a problem?	No
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)?	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	The person affected was not the user.
On average, number of pieces, pinches, dips, or rubs used	<blank>
Please select	<blank>
On average, number of pieces used	<blank>
Please select	<blank>
On average, number of dabs used	<blank>
Please select	<blank>

Reaction and Product Relatedness

How soon after the product was last used did the health problem occur?	15
Select Unit of Measure	minute(s)
Did the person stop using the product when he/she had the health problem?	Unknown

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 so far)?	1
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
Outcome to date	Recovered/Resolved
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?	Yes
Please describe the similar health problem or product problem	It happened once before after exposure to electric cigarette.
What are the main symptoms or health problems? (select up to 5)	<u>Digestive System</u> problem (such as: nausea/vomiting, stomach pain, diarrhea, constipation)

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	54
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	Advil. Effexor-EX, pseudoephedrine. Centrum Silver Vitamins for women. Glucosamine for Arthritis.

Attached Files

None

REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.CTP.V.V1
Report Category	Tobacco Product Report
Submitted	2014-01-31□15:44:51
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 (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 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 Logic, BLack label. Both Menthol and non-menthol cartridges.

Universal Product Code (UPC) from label <blank>

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 purchased? Yes

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 <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

When did the person open the package and start using the product that may have caused the health problem?	09/20/2013
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?	4
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?	Yes
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)?	Yes
Does the person who had the adverse event also drink alcohol?	Yes
Has the affected person used other tobacco products in the past?	No
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 the health problem occur?	<blank>
Select Unit of Measure	<blank>
Did the person stop using the product when he/she had the health problem?	No

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 so far)?	2
Select Unit of Time	month(s)
Please describe the health problem or product problem:	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 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? (Select one or more)	None of the above
Outcome to date	Ongoing
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?	No
Please describe the similar health problem or product problem	<blank>
What are the main symptoms or health problems? (select up to 5)	<u>Lungs or Breathing problem</u> (such as: cough, asthma, wheezing, lung infection)

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	25

occurred

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 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 INFORMATION

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	(b) (6)

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)

Contact Information - Sender

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? Yes

Preferred method of contact Email

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product? No

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

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? Yes

Description of other tobacco product type Electronic cigarettes

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?	<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	<blank>
On average, number of pieces, pinches, dips, or rubs used	<blank>
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)?	3
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?	No
Was the person evaluated by a healthcare professional?	Yes
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?	Yes
Please describe the similar health problem or product problem	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>Heart or Blood</u> problem (such as: chest pain, heart attack, high or low blood pressure, palpitations bleeding, clotting), <u>Mood or Mental health</u> problem (such as: anxiety, agitation, depression)

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	55
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	2014-02-06 01:30:51
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? Yes

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 the health problem?	10//2013
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 brand?	3
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?	No
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)?	Yes
Does the person who had the adverse event also drink alcohol?	No
Has the affected person used other tobacco products in the past?	Yes
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	1
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?	2

Select Unit of Measure	month(s)
Did the person stop using the product when he/she had the health problem?	Yes
Did the symptoms from the health problem go away or get better when the person stopped or reduced the amount of product used?	Unknown
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	<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)?	1
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 professional?	No
Has the person had a similar health problem or product problem?	No
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)	Burn

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 health problem	(b) (6)
Age of the person when the health problem occurred	50
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 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 Cafergot

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	(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 (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? Yes

Preferred method of contact Email

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 Vapor King

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 the health problem?	11/08/2013
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?	3
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?	Yes
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)?	Yes
Does the person who had the adverse event also drink alcohol?	No
Has the affected person used other tobacco products in the past?	Yes
Please describe anything else you think the FDA should know about this health problem	<blank>
On average, number of pieces, pinches, dips, or rubs used	1
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?	No

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 so far)?	1
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? (Select one or more)	Hospitalization
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
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?	No
Please describe the similar health problem or product problem	<blank>
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	66
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, Potasium 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	2014-02-18 10:53:17
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 (b) (6)
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 necessary? Yes
Preferred method of contact Email
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 Green Smart Living
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? 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 <blank>
Street Address Line 2 <blank>

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

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?	1
Select Unit of Measure	Months
Was the product being used when the health problem occurred?	<blank>
Did the person use this product before without a problem?	Yes
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)?	No
Does the person who had the adverse event also drink alcohol?	Yes
Has the affected person used other tobacco products in the past?	Yes
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	6
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? No

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)? 1

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? No

Was the person evaluated by a healthcare professional? No

Has the person had a similar health problem or product problem? No

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, 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 31

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person Generally healthy. Had a diagnosis of rheumatoid arthritis in college, however, no effects from this in 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 problem <blank>

Attached Files

None

REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.CTP.V.V1
Report Category	Tobacco Product Report
Submitted	2014-02-21 13:52:05
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) (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)

ZIP/Postal Code (b)

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

Preferred method of contact <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 <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? Yes

Description of other tobacco product type E 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 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?	<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>
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	<blank>
On average, number of pieces, pinches, dips, or rubs 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	week(s)
Did the person stop using the product when he/she had the health problem?	<blank>

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)?	<blank>
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?	Yes
Date the person was first seen by a healthcare professional for this health problem	02/18/2014
Please describe any treatment the person received including results of any tests (such as x-rays, lab results, or blood work)	Doxycycline and Hydrocodone-homatropine
Has the person had a similar health problem or product problem?	No
Please describe the similar health problem or product problem	<blank>
What are the main symptoms or health problems? (select up to 5)	<u>Lungs or Breathing problem</u> (such as: cough, asthma, wheezing, lung infection)

Affected Person

Gender Female

Pregnant No

Race (Select one or more) Unknown

Ethnicity Unknown

Birth date of the person who experienced the health problem	(b) (6)
Age of the person when the health problem occurred	57
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 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	(b) (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? <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 <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 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?	<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>
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	<blank>
On average, number of pieces, pinches, dips, or rubs 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?	<blank>

Problem Summary

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)?	2
Select Unit of Time	hour(s)
Please describe the health problem or product problem:	While eating dinner at (b) (6) last night in (b) (6), the person at the table next to me was smoking one of those e-cigarettes. The vapor cloud was big enough to come over 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?	No
Has the person had a similar health problem or product problem?	No
Please describe the similar health problem or product problem	<blank>
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> (such as: cough, asthma, wheezing, lung infection), <u>Mood or Mental health</u> problem (such as: anxiety, agitation, depression)

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	43
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 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 (b) (6)

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? Yes

Preferred method of contact Email

Sender Category Consumer/Concerned Citizen

Are you the person who experienced health problems associated with a tobacco product? No

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

Product Information

Brand Name or Product Name blu

Universal Product Code (UPC) from label <blank>

Did the product come from another country? Unknown

Product Type Other

When did the person purchase this product? 02/25/2014

Does the person still have the product? Yes

Description of other tobacco product type electronic cigarette

Do you know where the product was purchased? Yes

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 [redacted]

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 the health problem?	02/25/2014
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?	1
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?	No
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)?	Yes
Does the person who had the adverse event also drink alcohol?	Yes
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	<blank>
On average, number of pieces, pinches, dips, or rubs used	1
Please select	per day

Reaction and Product Relatedness

How soon after the product was last used did the health problem occur?	9
Select Unit of Measure	hour(s)

Did the person stop using the product when he/she had the health problem?	Yes
Did the symptoms from the health problem go away or get better when the person stopped or reduced the amount of product used?	No
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)?	18
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?	No
Was the person evaluated by a healthcare professional?	No
Has the person had a similar health problem or product problem?	No
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 (such as: nausea/vomiting, stomach pain, diarrhea, constipation)

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	44
Select Unit of Age	year(s)

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

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 Prilosec, Tramadol and Baclofyn

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 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 <blank>

Universal Product Code (UPC) from label <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 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	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)?	24
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?	No
Please describe the similar health problem or product problem	<blank>
What are the main symptoms or health problems? (select up to 5)	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 health problem (b) (6)

Age of the person when the health problem occurred 55

Select Unit of Age year(s)

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

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

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 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	2014-03-01 16:15:09
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 purchased? <blank>

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 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? <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 of pieces, pinches, dips, or rubs 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?	<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 so far)?	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? (Select one or more)	None of the above
Outcome to date	Ongoing
Was the person taken to an emergency facility?	No
Was the person evaluated by a healthcare professional?	Yes
Date the person was first seen by a healthcare professional for this health problem	12//2013
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?	Yes
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> (such as: cough, asthma, wheezing, lung infection)

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	None

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	2014-03-03 17:47:56
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 <blank>

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

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

Preferred method of contact Email

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 some type of e-cigarette product

Universal Product Code (UPC) from label <blank>

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

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)?	3
Select Unit of Time	week(s)
Please describe the health problem or product problem:	As an employee with the (b) (6) , I was forced to sit in an office where people used e-cigarettes (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.

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 professional?	No
Has the person had a similar health problem or product problem?	No
Please describe the similar health problem or product problem	<blank>
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> (such as: cough, asthma, wheezing, lung infection)

Affected Person

Gender Female

Pregnant No

Race (Select one or more) White

Ethnicity <blank>

Birth date of the person who experienced the health problem	<blank>
Age of the person when the health problem occurred	<blank>

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

Component Purchase Location

Component Manufacturer Information

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 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	the treatment was stay away from the e-cigarette vapor and keep those toxins out of my body!

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>

City/Town (b) (6)

State (b)

ZIP/Postal Code (b)

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

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

Preferred method of contact Email

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 Sweet Southern Vapes

Universal Product Code (UPC) from label <blank>

Did 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 the health problem?	02/20/2014
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?	2
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?	No
Did the person change the product in any way before using it (for example: removing a filter from a cigarette)?	No
On average, number of pieces, pinches, dips, or rubs used	<blank>
Please select	<blank>

Reaction and Product Relatedness

How soon after the product was last used did the health problem occur?	1
Select Unit of Measure	day(s)
Did the person stop using the product when he/she had the health problem?	No

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 so far)?	2
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? (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?	No
Has the person had a similar health problem or product problem?	No
Please describe the similar health problem or product problem	<blank>
What are the main symptoms or health problems? (select up to 5)	<u>Allergic</u> reaction, <u>Lungs or Breathing problem</u> (such as: cough, asthma, wheezing, lung infection), <u>Head or Neck</u> problem (such as: difficulty swallowing; change in speech, taste, hearing or vision; seizure, stroke), 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)
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	None

Product Components

Other Products Used

Other Tobacco Products Currently Used

Other Tobacco Products Used in the Past

Medications, Vitamins and Supplements

Attached Files

None

LAW OFFICES OF

(b) (6)

(b) (6)

September 24, 2013

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,

(b) (6)

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Consumer Report

CTP

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 sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	60 Years (b) (6)	☐ Female ☑ Male	184 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/26/2013	10/26/2013

5. Describe Event, Problem or Product Use Error

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 face and scalp 3) renal impairment progressed to direct and immediate effect as per doseage use. Have immediately ceased and am seeking ways to purge system. Please answer IMMEDIATELY with information as to treatment protocol (b) (6)
(b) (6)

6. Relevant Tests/Laboratory Data, Including Dates

symptoms apparent 2 weeks ago, isolated and confirmed 10/26/13 ceased use today
1) chronic diahrea for 2 weeks
2) developed chin rash 1 week ago, spread and worsening.

Drinking fluids, treating diahrea, seeking antidotes. Will begin organic natural vitamin C 4,800MDA and

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

Race:White Medical Conditions: high blood pressure, cardiac stent, CAD, PAD, kidney disease

symptoms easing with increased allery meds, cortizone, Loperamide Hydrochloride Allergies: life long chemical, food and environmental,
Contact info: (b) (6)
Symtomology: ...

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: E-Cig Juice PEG formula
Strength: 16mg nic
Manufacturer: CreateACig.com

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 OTC	As needed	Inhalation
#2		

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

#1 09/07/2013 - 10/26/2013
#2

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

#1 smoking cessation
#2

6. Lot #	7. Expiration Date
#1 N/A	#1
#2	#2

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

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

9. NDC # or Unique ID
N/A

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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

1. Name and Address

(b) (6)

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

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

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

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

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

... MDA

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 Information: former cigarette smoker, no alcohol
Missing info previous page: ceasing use yesterday and today, cortizone, increased allergy doseage.
Result some easing of symptoms
Symtomology: PEG (polyethelene glycol) toxicity RX Meds: metropolol, lisinopril, pravastatin, Zetia, plavix, nexium, hctz, chlorzoxazone, tramadol
Symtomology: PEG (polyethelene glycol) toxicity OTC Meds: asprin, melatonin, holy basil, clifornia poppy, stinging nettles, afrin, L-Lysine, Zyrtec, Claritan, Fish Oil, cortizone cream
Symtomology: PEG (polyethelene glycol) toxicity

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

Consumer Report CTP

U.S. Department of Health and Human Services

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	59 Years (b) (6)	☑ Female ☐ Male	270 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
10/02/2013	10/25/2013

5. Describe Event, Problem or Product Use Error

I have severe COPD and I also have heart rhythm problems. I was waiting in line at a local CVS pharmacy to get a RX filled. I started getting chest tightening and a tingling in my jaw and near the top of my left shoulder. I started feeling dizzy and a bit nauseous, and my heart started beating irregularly. I also started sweating somewhat profusely. Next to me was a nurse copiously and profusely puffing on an e-cigarette and exhaling the "vapor" in my face. When I asked her what it was she was using, she replied, "It's only harmless vapor being exhaled." The exhaled "smoke" wasn't as harmless ...

6. Relevant Tests/Laboratory Data, Including Dates

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

Race:White Medical Conditions: COPD, heart rhythm problems, Hashimoto's Allergies: Zantac, Lovenox, Xylitol, and bee stings Important Information: No smoking, no alcohol. Arthritis. RX Meds: levothyroxine, CPAP OTC Meds: occasional aspirin, Centrum Silver

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Name: e-cigarettes
Strength: unknown
Manufacturer: unknown
#2 Name:
Strength:
Manufacturer:

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

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

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

4. Diagnosis or Reason for Use (Indication)
#1 Bystander subjected to second-hand "vapor smoke" from e-
#2

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

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

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

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

PLEASE TYPE OR USE BLACK INK

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 "vapor 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 face. I did have systemic issues when she did do so. After the air cleared, the symptoms I had also cleared up.

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

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

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

U.S. Department of Health and Human Services

Consumer Report

CTP

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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

FDA USE ONLY

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	58 Years (b) (6)	☑ Female ☐ Male	127 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/06/2013	11/12/2013

5. Describe Event, Problem or Product Use Error

I am a 58 year old female, healthy, nonsmoker. I recently spent time socially in a place where 6 or 7 "e-cigarettes" were being used. It took me a little while to figure out that the sudden dizziness and difficulty breathing I was experiencing was related to the "harmless vapor" that the smokers were exhaling. I was using a menu to fan away the vapor the best I could (they all thought I had a 6 hour long hot flash Haha!) but by the end of the evening my throat was sore and constricted, my breathing impaired, and my clothing smelled of the sicky sweet scent of the various products in use. It ...

6. Relevant Tests/Laboratory Data, Including Dates

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

Race:-- Medical Conditions: Allergies: Important Information: RX Meds: OTC Meds:

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: e-cigarette
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

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

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

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

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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

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

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

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

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

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)

For VOLUNTARY reporting of adverse events and product problems

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

... took about 3 days for my throat to heal and my breathing to be normal. I am convinced that there are "secondhand smoke" issues for us non smokers in closed environments when these devices are in use. My request is that these issues be studied and that non-smoking establishments will restrict the use of these devices as a health issue for the non-users. Thank You, (b) (6)

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

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

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

U.S. Department of Health and Human Services

Internet Consumer Report

CTP

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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

FDA USE ONLY
Triage unit
sequence #

A. PATIENT INFORMATION

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

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply.

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
11/17/2013	11/21/2013

5. Describe Event, Problem or Product Use Error

I recently switched from cigerattes to the white rhino e cig liquid and When I stopped smoking the white rhino e cig liquid I started to suffer extreme anxiety symptoms. I was concerned about my breath constantly and suffered the side effects of an anxiety attack. It has been 6 days since I stopped smoking it and I still suffered some effects.

6. Relevant Tests/Laboratory Data, Including Dates

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

Race:White

Medical Conditions: High blood pressure/ high chloestrole

Allergies: none

Important Information:

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: white rhino e cig liquid
Strength: 25mg
Manufacturer: white rhino

#2 Name:
Strength:
Manufacturer:

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

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 11/08/2013 - 11/17/2013
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 To quit smoking cigs or find a better alternative
#2

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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

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

Phone #	E-mail
(b) (6)	

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

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

PLEASE TYPE OR USE BLACK INK

U.S. Department of Health and Human Services

Internet Consumer Report CTP

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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

V1

FDA USE ONLY

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6)
In confidence

2. Age at Time of Event or Date of Birth: 57 Years (b) (6)

3. Sex: ☑ Female ☐ Male

4. Weight: 200 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*: 11/23/2013

4. Date of this Report *(mm/dd/yyyy)*: 11/25/2013

5. Describe Event, Problem or Product Use Error

My coworker has started using ecigarettes in our office. I get headaches and a sore throat when she does. Last week, I developed bronchitis, fever, and cough. The healthcare worker asked if I am a smoker. (I have never smoked.)

6. Relevant Tests/Laboratory Data, Including Dates

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

Race: White

Medical Conditions: bronchitis

Allergies: (possibly) tetracycline

Important Information:

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: ecigarette
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount / Frequency / Route

#1
#2

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

#1
#2

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

#1
#2

5. Event Abated After Use Stopped or Dose Reduced?

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

6. Lot #

#1
#2

7. Expiration Date

#1
#2

8. Event Reappeared After Reintroduction?

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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

1. Name and Address

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

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

2. Health Professional? ☐ Yes ☐ No

3. Occupation

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

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

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

CTP

U.S. Department of Health and Human Services

Internet Consumer Report

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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

1/3

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) In confidence	46 Years (b) (6)	☐ Female ☑ Male	250 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
(b) (6)	12/21/2013

5. Describe Event, Problem or Product Use Error

While smoking my e-cigarette, Brand Smoke Magnetto, with an ultrafire protected lithium rechargeable battery and a Joytech pro 2 the joytech coil shorted out causing the battery which is supposed to have a circuit to protect from this exact type of short to outgass and explode. It ignited the gas and exploded cracking my upper denture, breaking my upper palate and nose and igniting my face and sinus cavity on fire. Iwas rushed to the county burn unit where they adressed my 1st and 2nd degree burns. We have since found that my spetum tore through my nasal cavity causing bone loss and possible ...

6. Relevant Tests/Laboratory Data, Including Dates

CTU

DEC 23 2013

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

Race:White

Medical Conditions: SLE, psoriatic arthritis, osteoporosis, and interstitial lung desease. Diabetes, pituitary tumor, hypothyroidism, hypogonadism,
---
Allergies: Comtrast dye, percocet, betadyne, imodium,

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: smok
Strength:
Manufacturer: smok cigarette

#2 Name:
Strength:
Manufacturer:

2 Dose or Amount	Frequency	Route
#1 nicotine	As needed	Taken by mouth
#2		

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

#1 03/04/2013 - 12/12/2013
#2

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

#1 Nicotine addiction
#2

5. Event Abated After Use Stopped or Dose Reduced?

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

8. Event Reappeared After Reintroduction?

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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

1. Name and Address

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

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

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

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

PLEASE TYPE OR USE BLACK INK

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

... necrosis. I have been adicicted to chewing tobacco for 10+ years and my pulmonologist recommended I try an e-cigarette 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 contacr (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:

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U.S. Department of Health and Human Services

Internet Consumer Report

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

1/2

FDA USE ONLY

Triage unit
sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6)
In confidence

2. Age at Time of Event or Date of Birth: 32 Years (b) (6)

3. Sex: ☐ Female ☑ Male

4. Weight: 180 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*: 12/23/2013

4. Date of this Report *(mm/dd/yyyy)*: 12/24/2013

5. Describe Event, Problem or Product Use Error

Back in early November I used a V2 electronic cigarette and felt as though my throat was closing up. Later in the day, I felt myself almost collapse and could not breathe. I am a registered nurse and the situation could have been extremely dangerous for myself and patients. I have used electronic cigarettes for years and just began using the V2 electronic cigarettes around October, approximately. Their printed ingredients are no different than any of the other products I've used. When I attempted to use their product again the next day I experienced nearly the same reaction. I contacted them ...

6. Relevant Tests/Laboratory Data, Including Dates

CTU
DEC 26 2013

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

Race: White

Medical Conditions: None

Allergies: Sulfa

Important Information:

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: Nicotine Cartridge Various flavo
Strength: 18mg and 24mg
Manufacturer: V2 Cigs www.v2cigs.com

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount / Frequency / Route

#1 -- / --
#2

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

#1 1 month
#2

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

#1 Nicotine withdrawal.
#2

5. Event Abated After Use Stopped or Dose Reduced?

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

6. Lot #

#1 VSBC (Batch #)
#2

7. Expiration Date

#1
#2

8. Event Reappeared After Reintroduction?

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

Catalog # / Expiration Date *(mm/dd/yyyy)*

Serial # / Other #

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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

1. Name and Address

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

Phone #: (b) (6)

E-mail: (b) (6)

2. Health Professional? ☐ Yes ☐ No

3. Occupation

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

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

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

... 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.

non-responsive

From: (b) (6)
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

non-responsive

[redacted]

From: [redacted]
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) [redacted]. 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) [redacted] 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,

(b) (6)

[redacted]

---------- Forwarded message ----------
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,

(b) (6)

---------- 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) (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.

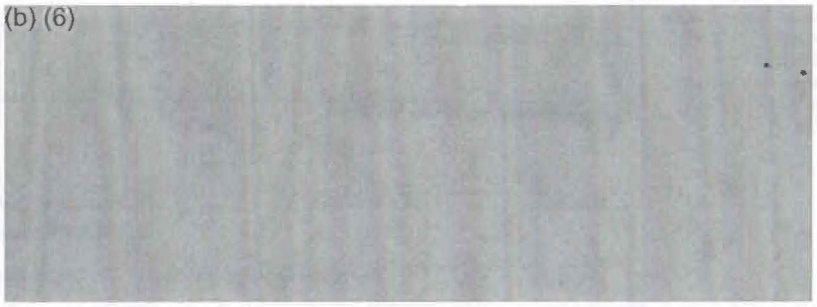
Vapor Hut could not provide any type of model number or UL number for the EVOD style cigarette.
They showed me a battery that is a little smaller in diameter than a AAA battery. I suspect that this battery has several wrist watch style batteries joined in series and packed with a plastic wrap.
Vapor purchases these EVOD cigarettes online from vivian@bilsencig.com.
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,

(b) (6)



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MEDWATCH

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FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	65 Years (b) (6)	☐ Female ☑ Male	185 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
01/04/2014	01/05/2014

5. Describe Event, Problem or Product Use Error

My husband has COPD and twice he has been in the presence of a person smoking a e cigarette. Both times after about 30 minutes to a hour of exposure (different room sizes) he experienced difficulty breathing and had to leave. He did not have oxygen on at the time of exposure but after leaving immediately put on oxygen. He continued to have difficulty breathing till the following day.

6. Relevant Tests/Laboratory Data, Including Dates

CTU

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

Race:White

Medical Conditions: COPD

Allergies: none

Important Information: smoked in the past

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: e cigarette
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

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

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

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

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

6. Lot #
#1
#2

7. Expiration Date
#1
#2

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

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

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

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

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

PLEASE TYPE OR USE BLACK INK

U.S. Department of Health and Human Services

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1/2

FDA USE ONLY
Triage unit
sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b)
In confidence

2. Age at Time of Event or Date of Birth: 26 Years (b) (6)

3. Sex: ☑ Female ☐ Male

4. Weight: 120 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event (mm/dd/yyyy): 12/09/2013

4. Date of this Report (mm/dd/yyyy): 02/07/2014

5. Describe Event, Problem or Product Use Error

Experienced red burning eyes after being in a closed room with someone smoking an e-cigarette. This happened on more than one occasion and there were several people with the same burning feeling in their eyes.

6. Relevant Tests/Laboratory Data, Including Dates

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

Race: White

Medical Conditions:

Allergies: Allergic to peanut butter (only within the last year), pollen, trees, I take zyrtec daily for this
---

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount / Frequency / Route

#1
#2

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

#1
#2

4. Diagnosis or Reason for Use (Indication)

#1
#2

5. Event Abated After Use Stopped or Dose Reduced?

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

6. Lot #

#1
#2

7. Expiration Date

#1
#2

8. Event Reappeared After Reintroduction?

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: E-cigarette/hookah

2. Common Device Name: E-cigarette/hookah

3. Manufacturer Name, City and State: Nemesis, RSST

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address

Name: (b) (6)
Address:

City: State: -- ZIP:

Phone #

E-mail: (b) (6)

2. Health Professional? ☐ Yes ☐ No

3. Occupation

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

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

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

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

CTP

U.S. Department of Health and Human Services

Internet Health Professional Report

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MEDWATCH

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FDA USE ONLY

Triage unit
sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	0	☑ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
(b) (6)	01/23/2014

5. Describe Event, Problem or Product Use Error

The Proprietor of CigaWatt (1208 N 7 HWY, Blue Springs, MO 64014) contacted NicVape customer service to report the event and request a complete ingredient list for the product. The Proprietor reported that a customer inhaled the product using an electronic cigarette device (type unknown) and had what appeared to be a severe allergic reaction. The customer was taken to the emergency room where they administered an IV and epinephrine. Customer requested ingredient lists to help physician identify which ingredient the individual is allergic to. Ingredient list was provided to vendor along with ...

6. Relevant Tests/Laboratory Data, Including Dates

Unknown

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

Unknown at this time

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: Great Balls of Fire
Strength:
Manufacturer: NicVape, Inc.

#2 Name:
Strength:
Manufacturer:

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

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

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

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

Unknown

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

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

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

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

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

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

... NicVape contact information for follow-up.