

#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## Report Identifying Information

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

(b) (6)

(max length: 50 characters)

Voluntary

Regulatory Status

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	<black></black>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	<black></black>
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	 <blank></blank>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	I am her mother

# **Problem Summary**

Problem Start Date 11/03/2018
Problem End Date 11/03/2018

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

My daughter had recently started vaping in an effort to quit smoking. On 11/3, she had a grand mal seizure. Subsequent neurological exams showed no evidence of scarring or any other cause for the seizure. The possibilities presented were: maternal hx of seizures (I had a seizure disorder as a child, but do not take meds and haven't had a seizure in over 25 years), quitting smoking/vaping, withdrawal from Percocet used for oral surgery pain and a combination of all triggers. I heard on the news this morning that the FDA is looking into the link between ecigs and seizures, so wanted to report.

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

None of the above

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

MRI, CT Scan, EEG, full blood and urine panel

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

5

Select Unit of Time

minute(s)

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

24

**Select Unit of Age** year(s)

Please list any known preexisting health problems for the affected person

Recent dental surgery, so was just coming off opiates for pain, maternal history of seizures. No other health problems; generally healthy.

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Advil, Percocet, Tylenol for pain due to dental surgery. Day of the seizure was the first day off meds.

## What are the main symptoms or health problems?

Term describing the health problem

Seizure grand mal

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal **Tobacco Product Type** 

vaporizers; E-liquids, e-juice or vape juice)

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** 

vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping Uses a tank or tank system product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Other

Describe other e-liquid flavor(s)

Unknown. This was a while ago and she has not used it since.

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown

When did the person purchase this product?

11/02/2018

**UNIVERSAL PRODUCT** CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

User/Consumer has the product

How was this product acquired?

In a Store

Do you know where the product was purchased?

<blank>

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

1

**Select Unit of Measure** 

Weeks(s)

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

6

**Select Unit of Measure** 

Hour(s)

How long has the person been using this particular brand or label?

**Select Unit of Measure** 

Weeks(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

## **Other Products Used**

#### **Other Tobacco Products**

# **Additional Information**

# **Attached Files**

None



#### REPORT INFORMATION

#### **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-03

FDA ICSR ID (b) (6)

Followup by using your

account

(b) (6)

# Proxy Report Information (not applicable if this is not a proxy report)

## **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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	(b) (6)
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	(b) (6)
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer, Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health	My teen daughter experienced the health problem

# **Problem Summary**

problem

**Problem Start Date** 

12/18/2018

**Problem End Date** 

03/14/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

My teen daughter had her first of three seizures on (or around) 12/18/18. Cat Scan, blood tests, MRI, all normal. She had the seizure at school in computer class. She had a second seizure in June of 2018. She was in a car with 3 other teens going to a local festival. After the second seizure, two different types of EEG tests were ran, a sleepdeprived EEG, and one that she wore the equipment for almost 72 hours. All tests were normal. She was then cleared to drive. She had her third seizure March 14 2019 WHILE DRIVING home from a friend's house. Again, ALL TESTS WERE NORMAL. She is now on Keppra to control seizures. PRECEDING ALL THREE SEIZURES, SHE HAD USED THE JUUL. That is the only common thing between all three occurrences. Her neurologist is planning to keep her on the Keppra and insists that in addition to waiting 6 more months before she drive again that she guit using the JUUL. After seeing the announcement that the FDA is investigating e-cigarette use and seizures, especially in teens, I wanted to share this information. No other test we have ran to this point has explained why she was having these seizures, so this could potentially be causing enough over-stimulation to cause her seizures.

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

None of the above

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

She had 3 ER visits after each seizure. MRI's, CAT Scans, EEG's, blood tests and urine tests were ran and all were normal. She is now on a daily dose of 750mg of Keppra and ordered to stop using the JUUL.

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

18

**Select Unit of Time** 

month(s)

What is the current status of the health problem?

Unknown

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each

affected person, if possible.)

User(s)

How many users were

affected?

<blank>

**Gender** Female

Pregnant <br/> <blank>

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

16

Select Unit of Age

year(s)

Please list any known preexisting health problems for

the affected person

Depression, anxiety

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Zoloft, Lithium

## What are the main symptoms or health problems?

Term describing the health problem

Seizures

# **Tobacco Products**

Tobacco Product Type	Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)
Tobacco Product Subtype	E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer
Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)	
Select all that apply to the e- liquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product	                         
Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)	Nicotine
Was the e-liquid dripped on to the atomizer or heating element?	Yes
Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")	JUUL
When did the person purchase this product?	 <blank></blank>
UNIVERSAL PRODUCT CODE (UPC) from Label	 <blank></blank>
Does the involved product device or package bear the "UL" symbol?	 <blank></blank>
Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)	I do not know how my teen was acquiring the JUUL as she is NOT 18
What is the country of manufacture of the tobacco product?	   

Where is the tobacco product now?

<blank>

How was this product

acquired?

<blank>

Do you know where the product was purchased?

No

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

## **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

Unknown

Describe what substances are being mixed with the tobacco product	<blank></blank>
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	2
Select Unit of Measure	Year(s)
How soon after the tobacco product was last used did the problem occur?	4
Select Unit of Measure	Month(s)
How long has the person been using this particular brand or label?	2
Select Unit of Measure	Year(s)
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

## **Other Products Used**

## **Other Tobacco Products**

# **Additional Information**

## **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## Report Identifying Information

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Voluntary

**Regulatory Status** Type of Submission

Initial

What type of report are you

submitting?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** (b) (6) **Confirm Email** (b) (6) **First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States** Street Address Line 1

Street Address Line 2 <blank>

City/Town (b) (6)

**State** 

**ZIP/Postal Code** 

**Sender Category** Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that

Consumer, Concerned citizen apply)

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

Yes

## **Problem Summary**

**Product Problem Type** (select all that apply)

Other

Describe the other product problem

Health issue.

In what setting(s) did this problem occur? (select all that apply)

One person using one or more product(s), Public indoor location (office, store, mall, restaurant, bar, school, sports arena), Other

Describe the other setting

**Denver International Airport** 

**Problem Start Date** 

01/18/2019

**Problem End Date** 

01/18/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

I had a grand mal seizure in the Denver International airport. There are reports that JUUL is being linked with the cause of the seizures. My seizure is registered with a Neurologist after being seen and concluded with no real cause of what happened. I think it is associated with using the JUUL as an alternative smoke.

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

Lasting disability or other permanent health problem

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Catscan, MRI, and Neurologist visit. I was admitted to the University of Colorado after having the seizure. They released me after about roughly three hours.

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

<blank>

**Select Unit of Time** 

<blank>

What is the current status of the health problem?

<blank>

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

Gender Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the

problem occurred

22

**Select Unit of Age** year(s)

Please list any known preexisting health problems for None. the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Multi Vitamin

## What are the main symptoms or health problems?

Term describing the health problem

Tonic-clonic seizures

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Disposable (non-refillable) product, Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Propylene Glycol

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Mint (such as wintergreen or spearmint)

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL

When did the person purchase this product?

06/07/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

Online Order

Do you know where the product was purchased?

No

**Manufacturer Name** 

Other

# **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) JUUL

**Country** United States

Phone <br/>
Street Address Line 1 <br/>
Street Address Line 2 <br/>
City/Town <br/>
State <br/>
ZIP/Postal Code <br/>
Web Address <br/>
Stank>

Email Address <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

# **Tobacco Product Use Details**

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	Every Day
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	1
Select Unit of Measure	Year(s)
How soon after the tobacco product was last used did the problem occur?	10
Select Unit of Measure	Day(s)
How long has the person been using this particular brand or label?	1
Select Unit of Measure	Year(s)
Did the person continue to use this tobacco product after the problem occurred?	No
Did this same or similar problem happen again after repeat use of the tobacco product?	N/A - Person did not restart use
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

I think that the JUUL is the cause of my seizure I had on January 18, 2019.

#### **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## Report Identifying Information

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

(b) (6)

(max length: 50 characters)

Regulatory Status Voluntary

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? Job Title **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States** Street Address Line 1 Street Address Line 2 <blank> City/Town (b) (6) State **ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer apply) Are you the person who experienced health Yes

## **Problem Summary**

problems associated with a

tobacco product?

Problem Start Date 10/16/2018
Problem End Date 10/16/2018

**Please describe the health** I was using a Juul E Cigarette device and after 1 hit of it, I blacked out **problem or product problem.** and I'm pretty sure I had a seizure.

The Attachments page will accept uploads of any records, pictures, or other information.

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

None of the above

Treatment Received (select all that apply)

Self-Treated

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

After waking up, I drank lots of water and a gatorade and went to bed as I felt completely awful.

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

6

**Select Unit of Time** 

hour(s)

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

year(s)

16

Please list any known preexisting health problems for the affected person

Select Unit of Age

Reynauds

#### **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

none

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Select all that apply to the electronic cigarette,

product (including electronic

**electronic nicotine or vaping** Uses prefilled cartridge, cart, cartomizers or carto.

waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

Purchased in a non-refillable disposable cartridge

electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Propylene Glycol

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

PAXLABS JUUL

When did the person purchase this product?

03/01/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

819913011375

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

From a Friend

Do you know where the product was purchased?

No

**Manufacturer Name** 

Other

#### **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) Juul

**Country** United States

Phone <br/> <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <br/> <blank>

State <br/> <blank>

ZIP/Postal Code <br/>
<b

Web Address <br/> <br/>

Email Address <br/> <blank>

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Rarely

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

7

Select Unit of Measure Month(s)

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

, 1

Select Unit of Measure Second(s)

How long has the person been using this particular brand or label?

7

Select Unit of Measure Month(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

Please only contact me VIA email as I am still underage and do not want my parents knowing about this issue that I had. I currently no longer use the product and never will again after this incident.

#### **Attached Files**

None



#### REPORT INFORMATION

## **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-03

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# **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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside YSRP)?

Yes

Describe who the problem was reported to

Doctors

# **Contact Information - Sender**

 <blank></blank>
(b) (6)
(b) (6)
(b) (6)
<black></black>
(b) (6)
(b) (6)
(b) (6)
United States
(b) (6)
(b) (6)
(b) (6)
(b) (6)
Consumer/Concerned Citizen (FdaTPR)
Other, Consumer, Concerned citizen
Parent
No
Father

# **Problem Summary**

Problem Start Date 01/04/2019

Problem End Date 04/03/2019

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

Grand mal seizures due to nicotine intoxication

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

Lasting disability or other permanent health problem, Life threatening, Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission, Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

currently now diagnosed with epilepsy. no seizure activity prior to smoking e cigarettes and juuls

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

15

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person none, had an abnormal EEG but had not been diagnosed with epilepsy until after first grand mal seizure where he had been HEAVILY VAPING for several months. Second grand mal he also had been heavily vaping and vaping heavily 5 minutes before the seizure.

# **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

# What are the main symptoms or health problems?

Term describing the health problem

Seizures

## **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Disposable (non-refillable) product, Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Power (watts) can be changed or adjusted, Button activated, Puff/flow activated

How has the electronic cigarette, electronic nicotine or vaping product been modified by the user? (select all that apply)

<blank>

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Tobacco, Mint (such as wintergreen or spearmint), Fruit, Combination/mixture of flavors

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

jul

When did the person purchase this product?

09/03/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

From a Friend

Do you know where the product was purchased?

Nο

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

# **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	6
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the problem occur?	6
Select Unit of Measure	Week(s)
How long has the person been using this particular brand or label?	6
Select Unit of Measure	Month(s)

Month(s) Select Unit of Measure

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

**Full Tobacco Product Part** Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

jul

**Tobacco Product Part Type** 

Cartridge

When was this tobacco product part purchased or acquired?

09/10/2018

**UNIVERSAL PRODUCT CODE (UPC) from Label** 

<blank>

Any other identifying tobacco product part codes(e.g. SKU, item/catalog number)

<blank>

What is the country of

manufacture of the tobacco

product part?

**United States** 

Where is the tobacco product part now?

Product was discarded

Do you know who

manufactured this tobacco

product part?

No

#### **Tobacco Product Part Purchase Location**

How was this tobacco product part acquired?

From a Friend

**Purchase Location Name** 

school

Country

United States

Phone

<blank>

Street Address Line 1

<blank>

Street Address Line 2

<blank>

City/Town

oklahoma city

State

Ohio

**ZIP/Postal Code** 

<blank>

Web Address

<blank>

**Email Address** 

<blank>

## **Tobacco Product Part Manufacturer Information**

State

<blank>

State/Province

<blank>

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

Vaping has almost killed my 15 year old son. He never had a seizure until vaping. His first two seizures were directly after heavily vaping.

## **Attached Files**

None



#### REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

(b) (6)

(max length: 50 characters)

Voluntary

Regulatory Status

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

Describe who the problem was reported to

<blank>

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

Organization Name <br/> <br/>

Confirm Email (b) (6)

First Name (b) (c)

Last Name (b) (6)

Did you report the problem to the manufacturer?

Job Title <br/>
Phone <br/>
<b

Email (If prefilled, changing this email address will not change your Login email ID)

(b) (6)

**Country** United States

Street Address Line 1 <blank>
Street Address Line 2 <blank>
City/Town <blank>

State (b) (6)

ZIP/Postal Code <br/>
<b

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned
Citizen Type (select all that

apply)

Consumer

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

Yes

# **Problem Summary**

Problem Start Date 02/09/2018

Problem End Date <br/>
<

Please describe the health problem or product problem. onset of seizures

The Attachments page will accept uploads of any records, pictures, or other information.

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

Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

MRI, CT scan, blood tests

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

Select Unit of Time

year(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

<blank>

**Gender** Female

**Pregnant** No

Race (Select all that apply) Asian

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

32

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

existing health problems for no pre-existing health conditions

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

birth control medication, cranberry vitamins

## What are the main symptoms or health problems?

Term describing the health problem

Seizures

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to
the electronic cigarette, Recharge
electronic nicotine or vaping carto (tha
product (including electronic activated
waterpipe)

Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Uses a tank or tank system, Button activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

Purchased for use in a capsule, tank or refillable cartridge

electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Coloring Agents, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Menthol, Fruit, Combination/mixture of flavors

Was the e-liquid dripped on to the atomizer or heating element?

Yes

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Volcano Premium Eliquid

When did the person purchase this product?

01/24/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

No

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco

e tobacco United States

product?

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

Yes

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location 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> **Email Address** <blank>

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

On average, how often is this tobacco product used? Every Day

Are other substances being mixed in with the tobacco No product when used?

Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	5
Select Unit of Measure	Year(s)
How soon after the tobacco product was last used did the problem occur?	2
Select Unit of Measure	Hour(s)
How long has the person been using this particular brand or label?	5
Select Unit of Measure	Year(s)
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

# **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

# **Other Tobacco Products**

**Tobacco Product Type** Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

No

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

#### **Attached Files**

None



#### REPORT INFORMATION

# **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-03

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# **Report Identifying Information**

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Voluntary

Regulatory Status

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	 <blank></blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<black></black>
Job Title	 <blank></blank>
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Other, Concerned citizen
Describe other consumer/ concerned citizen type	PARENT
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Mother

## **Problem Summary**

Problem Start Date 10/13/2018

Problem End Date <br/>
<

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information. My son had his first seizure on 10/13, another one on 10/14. Went into hospital for testing for 4 days. No cause was found. Had another 3 seizures on 11/22, and another 2 on 11/23. As more and more news reports come out relating seizures to vaping, and knowing my son was vaping excessively, and also vaping extremely high potency nicotine-I truly believe his seizures are the cause of vaping. He had NO other health issues. Now has a epileptologist and is on medication for a minimum of two years, and will continually be tested.

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

Life threatening, Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission, Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Ambulance to ER with 1st seizure. He was released after CT scan, blood tests. Couldn't find cause of seizures. Another ambulance visit to ER same night. Admitted for 4 days. Multi day EEG, MRI, blood tests, urine tests. Still could find no cause. 11/22- 3 seizures. Chipped 1/2 his tooth off that required visit to dentist to fix. 11/23 2 seizures. Visit to ER to get hydrated as couldn't stop having seizures which were stuck in a loop with constant vomiting.

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

5

**Select Unit of Time** 

month(s)

What is the current status of the health problem?

Not Recovered or Unresolved

# Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

Gender Male

White Race (Select all that apply)

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the

problem occurred

17

Select Unit of Age year(s)

Please list any known preexisting health problems for Random migraines. Unrelated. the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Sometimes took Tylenol or Excedrin Migraine for headaches.

# What are the main symptoms or health problems?

Term describing the health problem

Tonic-clonic seizures

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-liquid, e-juice or vape juice (purchased separately) Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Glycerin, Propylene Glycol

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Mad Hatter Salts Luau Lemonade flavor, Juul, I'm sure others.

When did the person purchase this product?

//2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

Other

If other, please describe

Unknown. My son was under 18 so no idea how he got it.

Do you know where the product was purchased?

No

**Manufacturer Name** 

Other

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) Mad Hatter

**Country** United States

Phone <br/> <br/>

Street Address Line 1 19801 Nordhoff Pl

Street Address Line 2 #105

City/Town Chatsworth

**State** California

ZIP/Postal Code 91311

Web Address www.madhatterjuice.com

Email Address info@madhatterjuice.com

## **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

<blank>

Did the problem occur with first time use of the tobacco product?

No

How long has the person been using this type of tobacco product?

<blank>

**Select Unit of Measure** 

<blank>

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

<blank>

**Select Unit of Measure** 

<blank>

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Unknown

Did this same or similar problem happen again after repeat use of the tobacco product?

<blank>

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

<blank>

## **Tobacco Product Parts**

Full Tobacco Product Part Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Suorin Air

**Tobacco Product Part Type** 

Other

Description of Other
Tobacco Product Part Type

Pod System

When was this tobacco product part purchased or acquired?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Any other identifying tobacco product part

codes(e.g. SKU, item/catalog

<blank>

number)

What is the country of manufacture of the tobacco

<blank>

product part?

Where is the tobacco product part now?

<blank>

Do you know who

manufactured this tobacco

<blank>

product part?

#### **Tobacco Product Part Purchase Location**

Purchase Location Name <br/>
<

**Country** United States

Phone <br/> <br/> <br/> <br/> <br/> <br/>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <br/> <blank>

State <br/> <blank>

ZIP/Postal Code <br/>
<b

Web Address <br/> <blank>

Email Address <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

# **Tobacco Product Part Manufacturer Information**

State <br/>
State/Province <br/>
<br/>
State/Province

#### Other Products Used

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

Tobacco Product Type

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please

enter "unknown")

Is the tobacco product currently being used?

Juul

<blank>

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. I truly believe my son's seizures were caused by vaping. The day of the first seizure he had told the ER he was 'vaping all day'. He is 18 now and I am not aware if he is still vaping. I believe that the vaping he was doing was out of control as he was a nicotine addict, and this caused his seizure disorder. He's not diagnosed with Epilepsy. His epileptologist is aware that there may be a link between vaping and seizures- whether they cause them directly or they are a trigger. My son has a 15 year old younger brother who is also into this- it really must be stopped.

#### **Attached Files**

FILENAME IMG\_8744.JPG

**Description of Attachment** Ejuice

Attachment Type Photograph/Digital Image

**FILENAME** fullsizeoutput\_1814.jpeg

**Description of Attachment** 

Attachment Type Photograph/Digital Image

**FILENAME** fullsizeoutput\_1812.jpeg

**Description of Attachment** 

Attachment Type Photograph/Digital Image

FILENAME IMG\_8753.JPG

**Description of Attachment** 

Attachment Type Photograph/Digital Image

FILENAME IMG\_8749.JPG

**Description of Attachment** 

Attachment Type Photograph/Digital Image



#### REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Voluntary

**Regulatory Status** Type of Submission

Initial

What type of report are you

submitting?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? **Job Title** <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States** Street Address Line 1 Street Address Line 2 <blank> City/Town **State ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer apply) Are you the person who experienced health Yes problems associated with a tobacco product?

# **Problem Summary**

Product Problem Type (select all that apply)

Damaged, broken, or defective product, Leaked, Damaged, broken or defective part

In what setting(s) did this problem occur? (select all that apply)

One person using one or more product(s), Public outdoor location (park, stadium, hiking trail)

**Problem Start Date** 

06//2015

**Problem End Date** 

06//2015

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

This was a few years ago but I just found out about this page, a friend of mine who works in public health education forwarded it to me as they were told about this incident immediately after it occurred in 2015. I had just started using e-cigs in their first forms, and the company who sold mine to me suggested using a refillable cartridge in order to cut down on waste and costs. The first time I used it, before I had ever even refilled it, I was out on the town with a date and the moment I started inhaling I immediately blacked out and fainted. I had not been consuming alcohol. When I came to moments later date was so freaked they nearly called an ambulance, I was lucky I hadn't hurt my head in the fall. We left and when I got home we realized it was the e-cig that caused it after we looked up nicotine poisoning symptoms.

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

<blank>

Treatment Received (select all that apply)

Self-Treated

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

<blank>

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

30

**Select Unit of Time** 

minute(s)

What is the current status of the health problem?

Recovered or Resolved

# Affected Person

Who was affected by this tobacco problem? (Select

User(s)

one) (Please submit a separate report for each affected person, if possible.)

How many users were

affected?

Gender Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the

problem occurred

33

**Select Unit of Age** year(s)

Please list any known preexisting health problems for <blank>

the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

# What are the main symptoms or health problems?

Term describing the health problem

Unconsciousness

#### **Tobacco Products**

batch code)

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice) E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** vaporizer Select all that apply to the electronic cigarette, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the electronic nicotine or vaping user) product (including electronic waterpipe) Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, Purchased for use in a capsule, tank or refillable cartridge electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the Nicotine, Flavor(s) following? (select all that apply) What type(s) of flavor(s) does the e-liquid contain? Tobacco (select all that apply) Was the e-liquid dripped on to the atomizer or heating No element? Full Tobacco Product Name, including Brand and Sub-Unknown Brand (if unknown, please enter "unknown") When did the person 06//2015 purchase this product? **UNIVERSAL PRODUCT** <blank> CODE (UPC) from Label Does the involved product device or package bear the Don't Know "UL" symbol? Any other identifying tobacco product codes (for example, SKU, item/catalog <blank> number, manufacturing date/

What is the country of manufacture of the tobacco <blank>

product?

Where is the tobacco

product now?

<blank>

How was this product

acquired?

<blank>

Do you know where the product was purchased?

<blank>

**Manufacturer Name** 

Other

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

## **Tobacco Product Manufacturer Information**

**Manufacturer Name (Other)** <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> **Email Address** <blank>

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco Yes product?

How long has the person been using this type of tobacco product?

<blank>

**Select Unit of Measure** 

<blank>

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

60

**Select Unit of Measure** 

Day(s)

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

Tobacco	<b>Product</b>	<b>Parts</b>

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

**Attached Files** 

None



#### REPORT INFORMATION

## **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-03

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# **Report Identifying Information**

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	(b) (6)
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	Na
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	 <blank></blank>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Father

# **Problem Summary**

Problem Start Date 08/12/2013

Problem End Date 08/12/2017

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

Seizures starting in 2013 and currently having them. Son was vaping during years involved.

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

Lasting disability or other permanent health problem, Adverse pregnancy outcome including birth defects, Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

On seizure meds

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Male

Race (Select all that apply) V

White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

15

**Select Unit of Age** 

year(s)

Please list any known preexisting health problems for the affected person

<blank>

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

## What are the main symptoms or health problems?

Term describing the health problem

Focal seizures

## **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** 

vaporizer

Disposable (non-refillable) product, Rechargeable product, Uses Select all that apply to the electronic cigarette. prefilled cartridge, cart, cartomizers or carto., Uses refillable cartridge,

electronic nicotine or vaping cart, cartomizers or carto (that are filled by the user), Uses a tank

waterpipe)

product (including electronic or tank system, Modified: the original product was modified, Button activated, Puff/flow activated

How has the electronic cigarette, electronic nicotine or vaping product been modified by the user? (select all that apply)

The battery or power source has been changed, The heating element or atomizer has been changed. The tank system has been changed

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Describe the e-liquid mix

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Glycerin

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit, Candy or Chocolate

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

**Full Tobacco Product Name.** including Brand and Sub-Brand (if unknown, please enter "unknown")

Various.

When did the person purchase this product?

04/03/2019

**UNIVERSAL PRODUCT** CODE (UPC) from Label

<blank>

Does the involved product

Don't Know

device or package bear the "UL" symbol?

Any other identifying

No

tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

batch code)

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

Yes

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location Name** <blank> Country <blank> **Phone** <blank> **Street Address Line 1** <blank> **Street Address Line 2** <blank> City/Town <blank> <blank> State **ZIP/Postal Code** <blank> Web Address <blank> **Email Address** <blank>

## **Tobacco Product Manufacturer Information**

# **Tobacco Product Use Details**

How was the tobacco product used?	<blank></blank>
On average, how often is this tobacco product used?	Every Day
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	Yes
How long has the person been using this type of tobacco product?	<blank></blank>
Select Unit of Measure	<black></black>
How soon after the tobacco product was last used did the problem occur?	<black></black>
Select Unit of Measure	Hour(s)
How long has the person been using this particular brand or label?	<blank></blank>
Select Unit of Measure	<blank></blank>
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

**Attached Files** 

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Did you report the problem to the manufacturer?

No

Job Title <br/>
Phone <br/>
<b

Email (If prefilled, changing this email address will not change your Login email ID)

<blank>

**Country** United States

Street Address Line 1 <blank>
Street Address Line 2 <blank>
City/Town <blank>
State <blank>
ZIP/Postal Code <blank>

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that

apply)

Consumer

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

Yes

# **Problem Summary**

**Please describe the health** Had hit juul a few times prior to falling asleep, have been juuling **problem or product problem.** for about 1 year with no health problems. Started to flail around a

The Attachments page will accept uploads of any records, pictures, or other information.

few hours after, with eyes rolling around in back of head and non responsive for about 30 minutes. "Woke up" in back of ambulance and was taken to ER to have fluids given and tests ran.

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

None of the above

**Treatment Received (select** all that apply)

Emergency Room Visit Without Hospital Admission

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

45

**Select Unit of Time** 

minute(s)

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Male Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

17

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

Mild asthma

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Eyes rolling

## What are the main symptoms or health problems?

Term describing the health problem

Other

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

Purchased in a non-refillable disposable cartridge

electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the Nicotine, Flavor(s), Propylene Glycol following? (select all that apply) What type(s) of flavor(s) does the e-liquid contain? Tobacco, Menthol, Mint (such as wintergreen or spearmint), Fruit (select all that apply) Was the e-liquid dripped on to the atomizer or heating Unknown element? Full Tobacco Product Name, including Brand and Sub-Juul Labs Brand (if unknown, please enter "unknown") When did the person <blank> purchase this product? UNIVERSAL PRODUCT <blank> CODE (UPC) from Label Does the involved product device or package bear the <blank> "UL" symbol? Any other identifying tobacco product codes (for example, SKU, item/catalog <blank> number, manufacturing date/ batch code) What is the country of manufacture of the tobacco <blank> product? Where is the tobacco User/Consumer has the product product now? How was this product In a Store acquired? Do you know where the <blank> product was purchased?

## **Tobacco Product Packaging and Portions**

<blank>

**Manufacturer Name** 

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is **Every Day** this tobacco product used?

Are other substances being mixed in with the tobacco No product when used?

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of 1 tobacco product?

**Select Unit of Measure** Year(s)

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

**Select Unit of Measure** 

How long has the person been using this particular

brand or label?

Hour(s)

5

**Select Unit of Measure** Year(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products Yes (either currently or in the past)?

## **Other Tobacco Products**

**Tobacco Product Type** Cigarette

**Tobacco Product Subtype** <black>

**Full Tobacco Product Name** including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

No

#### **Other Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** <blank>

**Full Tobacco Product Name** including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

<blank>

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

#### **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

(b) (6)

Regulatory Status Vo

Voluntary

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email** <blank> **First Name** <blank>

**Last Name** <blank>

Did you report the problem <blank> to the manufacturer?

Job Title <blank> **Phone** <blank>

Email (If prefilled, changing this email address will not change your Login email ID)

<blank>

Country <blank> Street Address Line 1 <blank> Street Address Line 2 <blank> City/Town <blank>

State <blank> **ZIP/Postal Code** <blank>

**Sender Category** Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that

apply)

Consumer

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

Yes

# **Problem Summary**

**Problem Start Date** <blank> **Problem End Date** <blank>

Please describe the health

I experienced three seizures, and i believe they all may have been problem or product problem. related to juuling. My first seizure occured in the freezing cold of 2017 The Attachments page will accept uploads of any records, pictures, or other information.

in december. My mom found me passed out in the driveway in subzero temps. We didn't even know it occured until I had another one in the summer of that year. All I know is that in all 3 incididents I had hit my juul within 15 minutes of the seizure occuring.

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

Life threatening

**Treatment Received (select** all that apply)

Emergency Room Visit Without Hospital Admission

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

**Select Unit of Time** 

year(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

//2000

Age of the person when the problem occurred

18

Select Unit of Age

year(s)

Please list any known preexisting health problems for ADHD the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications. vitamins, and/or supplements taken around the time of the health problem.

Vyvanse

## What are the main symptoms or health problems?

Term describing the health problem

Seizure grand mal

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

<blank> **Tobacco Product Subtype** 

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

When did the person

purchase this product?

UNIVERSAL PRODUCT CODE (UPC) from Label

Does the involved product device or package bear the

"UL" symbol?

<blank>

<blank>

<blank>

Juul

Any other identifying tobacco product codes (for example, SKU, item/catalog

number, manufacturing date/

batch code)

<blank>

What is the country of manufacture of the tobacco <blank>

product?

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

<blank>

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

## **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

<blank>

Are other substances being mixed in with the tobacco product when used?	<blaue></blaue>
Did the problem occur with first time use of the tobacco product?	<blank></blank>
How long has the person been using this type of tobacco product?	<blaue></blaue>
Select Unit of Measure	<blank></blank>
How soon after the tobacco product was last used did the problem occur?	<blank></blank>
Select Unit of Measure	<blank></blank>
How long has the person been using this particular brand or label?	<blaue></blaue>
Select Unit of Measure	<blank></blank>
Did the person continue to use this tobacco product after the problem occurred?	<blaue></blaue>
Did this same or similar problem happen again after repeat use of the tobacco product?	<blank></blank>
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	<blank></blank>

# **Tobacco Product Parts**

# **Other Products Used**

# **Other Tobacco Products**

# **Additional Information**

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	 <blank></blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	   
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	       
Street Address Line 2	   
City/Town	   
State	(b) (6)
ZIP/Postal Code	   
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Wife

## **Problem Summary**

Product Problem Type (select all that apply)

Other

Describe the other product problem

It caused my wife to pass out.

In what setting(s) did this problem occur? (select all that apply)

In the place where I live

**Problem Start Date** 

03/14/2019

**Problem End Date** 

04/03/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

My wife has been smoking an e-cigarette (Juul) for the past year. Last month she passed out while in the shower and was unconscious for 2 minutes. I called 911 and we went to the emergency room. The doctors did not know what happened and said she might have been dehydrated so they let us go. A week went by and she continued to smoke the e-cigarette and it happened again. She passed out a second time this time only for 30 seconds but she fell and hit her head causing her to get stitches above her eye. We still had to call 911 and go to emergency room with no answers. My wife is healthy and has never had any of these issues before. She is no longer smoking the e-cigarette and we have had no issues since. I am not a medical expert but I know it was cause by the Juul.

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

Life threatening, Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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)

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select

User(s)

one) (Please submit a separate report for each affected person, if possible.)

How many users were

affected?

Gender Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the

problem occurred

35

**Select Unit of Age** year(s)

Please list any known preexisting health problems for None the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

# What are the main symptoms or health problems?

Term describing the health problem

Fainting

#### **Tobacco Products**

batch code)

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice) E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** vaporizer Select all that apply to the electronic cigarette, Rechargeable product, Uses prefilled cartridge, cart, cartomizers or electronic nicotine or vaping carto. product (including electronic waterpipe) Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, Purchased in a non-refillable disposable cartridge electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the Nicotine, Flavor(s) following? (select all that apply) What type(s) of flavor(s) does the e-liquid contain? Tobacco, Fruit (select all that apply) Was the e-liquid dripped on to the atomizer or heating Unknown element? Full Tobacco Product Name, including Brand and Sub-Juul Brand (if unknown, please enter "unknown") When did the person 02/24/2019 purchase this product? **UNIVERSAL PRODUCT** <blank> CODE (UPC) from Label Does the involved product device or package bear the Don't Know "UL" symbol? Any other identifying tobacco product codes (for example, SKU, item/catalog <blank> number, manufacturing date/

What is the country of

manufacture of the tobacco United States

product?

Where is the tobacco

product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

Yes

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location Name** <blank>

**United States** Country

**Phone** <blank>

**Street Address Line 1** <blank>

**Street Address Line 2** <blank>

City/Town <blank>

**State** New York

**ZIP/Postal Code** <blank>

**Web Address** <blank>

**Email Address** <blank>

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco product?

No

How long has the person been using this type of tobacco product?

<blank>

**Select Unit of Measure** 

Month(s)

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

<blank>

**Select Unit of Measure** 

Minute(s)

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

No

**Tobacco Product Parts** 

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

**Attached Files** 

None



### REPORT INFORMATION

### **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-03

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# **Report Identifying Information**

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



Regulatory Status Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside SRP)?

Yes

Describe who the problem was reported to

Had two separate events that required hospital visit and afterwards physician care

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States** Street Address Line 1 Street Address Line 2 <blank> City/Town (b) (6) State **ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer apply)

Yes

# **Problem Summary**

problems associated with a

Are you the person who experienced health

tobacco product?

 Problem Start Date
 09/08/2018

 Problem End Date
 09/30/2018

**Please describe the health** Morning of September 8th while in the shower had a black out/seizure; **problem or product problem.** confusion unable to talk, trouble walking. No memory of the event. This

The Attachments page will accept uploads of any records, pictures, or other information.

also happened on Jan 22nd, 2019---last thing I remember is getting in shower. Was found on floor by daughter four hours later. Same issues as previously on Sept 8th

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

Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

ER visit with admission. Multiple tests during hospital and afterwards with neurologist. If interested I can provide reports but had many tests done. And after 2nd event am still undergoing more tests.

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

9

**Select Unit of Time** 

month(s)

What is the current status of the health problem?

Unknown

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

<blank>

Gender Female
Pregnant <br/>
<br/>
<br/>
<br/>
Plank>

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

57

Select Unit of Age year(s)

Please list any known prethe affected person

existing health problems for High blood pressure arthritis back pain

### **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

tramadol, dicyclomine, gabapentin and losartin

### What are the main symptoms or health problems?

Term describing the health problem

Seizure

### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

**Nicotine** 

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the

<blank>

"UL" symbol?

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

Unknown if this is cause. Use Juul daily since August 20, 2018.

What is the country of manufacture of the tobacco

product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

<blank>

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

<blank>

**Select Unit of Measure** 

Month(s)

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

2

**Select Unit of Measure** 

Week(s)

How long has the person been using this particular brand or label?

7

**Select Unit of Measure** 

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

**Tobacco Product Type** Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

American spirit

Is the tobacco product currently being used?

No

### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. I only used for 2 weeks when first episode happened. During course of testing I asked numerous time if this could be related to Juul usage. I had never experienced anything close to the problem before. The neurologist determined the first episode as a "one time neurological event"---all the testing done was negative. The hospital doctors felt it was medication realted. Four months later (01/22/2019) the same type of episode/seizure occurred. Very scary and unsettling. I again went under many tests at hospital and neurologist did not see anythign

that may have caused it. We asked again at hospital and neuro appt if Juul could be related---was told they did not feel related at all and had not heard of any of this type events related to e cigarettes. I have an appointment on April 11th with the neurologist to get results of a 2 day test (hoping something found) and where to from here. I saw the report on Nightly News tonight and that is the reason I am reporting this now. I have printed the story on Juul and seizures and will take to my neuro at my appointment. I have many many test results if you are interested in them. Sorry for the long winded response but my life has been turned upside down by these recent events. Thank you.

### **Attached Files**

None



### REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Organization Name

(b) (6)

Confirm Email

(b) (6)

First Name

(b) (6)

(b) (6)

Did you report the problem to the manufacturer?

Job Title (b) (6)

Email (If prefilled, changing this email address will not change your Login email ID)

(b) (6)

<blank>

Country <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned
Citizen Type (select all that

apply)

**Phone** 

Consumer, Concerned citizen

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

Yes

# **Problem Summary**

 Problem Start Date
 06/20/2018

 Problem End Date
 04/03/2019

**Please describe the health** I have had multiple seizure like episodes as well as other neurological **problem or product problem.** symptoms such as brain fog, slurring of speech, head burning and

The Attachments page will accept uploads of any records, pictures, or other information.

more.. This has been an on going thing for months and no doctor can find out what's going on. This all started shortly after I started smoking the JUUL.

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

Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

I had 3 brain MRIs, an EEG, an EKG, a tilt table test, and blood work

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

10

**Select Unit of Time** 

month(s)

What is the current status of the health problem?

Not Recovered or Unresolved

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Female

Pregnant No

Race (Select all that apply) White

**Ethnicity** Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

year(s)

23

Please list any known preexisting health problems for <blank> the affected person

Select Unit of Age

### **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

# What are the main symptoms or health problems?

Term describing the health problem

Seizures

# What are the main symptoms or health problems?

Term describing the health problem

Slurred speech

# What are the main symptoms or health problems?

Term describing the health problem

Tremor

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** <blank>

**Full Tobacco Product Name**, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

05/30/2018

UNIVERSAL PRODUCT **CODE (UPC) from Label** 

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of

manufacture of the tobacco **United States** 

product?

Where is the tobacco

product now?

User/Consumer has the product

How was this product

acquired?

<blank>

Do you know where the product was purchased?

No

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

### **Tobacco Product Purchase Location**

**Purchase Location Name** <blank> <blank> Country **Phone** <blank> **Street Address Line 1** <blank> **Street Address Line 2** <blank> City/Town <blank> State <blank> **ZIP/Postal Code** <blank> **Web Address** <blank> **Email Address** <blank>

# **Tobacco Product Manufacturer Information**

### **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

On average, how often is this tobacco product used? Every Day

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person	
been using this type of	10
tohacco product?	

0

**Select Unit of Measure** 

Month(s)

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

1

**Select Unit of Measure** 

Month(s)

How long has the person been using this particular brand or label?

10

**Select Unit of Measure** 

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

### **Tobacco Product Parts**

### **Other Products Used**

### **Other Tobacco Products**

# **Additional Information**

# **Attached Files**

None



### REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

(b) (6)

(max length: 50 characters)

Voluntary

Type of Submission

**Regulatory Status** 

Initial

What type of report are you

submitting?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

### **Contact Information - Sender**

**Organization Name** <blank> **Confirm Email** <blank> **First Name** <blank> **Last Name** <blank>

Did you report the problem <blank> to the manufacturer?

Job Title <blank> **Phone** <blank>

Email (If prefilled, changing this email address will not <blank> change your Login email ID)

Country <blank> Street Address Line 1 <blank> Street Address Line 2 <blank> City/Town <blank> **State** <blank> **ZIP/Postal Code** <blank>

**Sender Category** Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that apply)

Concerned citizen

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

No

Describe your relationship to the person who experienced the health problem

It was a friend of my son's

## **Problem Summary**

Product Problem Type (select all that apply)

Other

Describe the other product problem

<blank>

In what setting(s) did this problem occur? (select all that apply)

One person using one or more product(s), Public indoor location (office, store, mall, restaurant, bar, school, sports arena)

**Problem Start Date** 

02/27/2019

**Problem End Date** 

<blank>

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

My son's friend from school Vaped at school, had a seizure and began vomiting and choking.

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

<blank>

Treatment Received (select all that apply)

<blank>

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

<blank>

**Select Unit of Time** 

lasted so far?

<blank>

What is the current status of the health problem?

<blank>

# **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Female Gender **Pregnant** Unknown

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

<blank>

Age of the person when the

**Select Unit of Age** 

14

problem occurred

year(s)

Please list any known preexisting health problems for <blank> the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

# What are the main symptoms or health problems?

Term describing the health problem

Seizure

### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** <blank>

**Full Tobacco Product Name**, including Brand and Sub-Unknown Brand (if unknown, please enter "unknown") When did the person <blank> purchase this product? UNIVERSAL PRODUCT <blank> CODE (UPC) from Label Does the involved product device or package bear the <blank> "UL" symbol? Any other identifying tobacco product codes (for example, SKU, item/catalog <blank> number, manufacturing date/ batch code) What is the country of manufacture of the tobacco <blank> product? Where is the tobacco <blank> product now? How was this product <blank> acquired? Do you know where the <blank> product was purchased?

**Manufacturer Name** 

# **Tobacco Product Packaging and Portions**

<blank>

# **Manufacturer Investigation Information**

**Tobacco Product Purchase Location** 

### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

<blank>

On average, how often is this tobacco product used?

<blank>

Are other substances being mixed in with the tobacco product when used?

<blank>

Did the problem occur with first time use of the tobacco product?

<blank>

How long has the person been using this type of tobacco product?

<blank>

**Select Unit of Measure** 

<blank>

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

<blank>

**Select Unit of Measure** 

<blank>

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

<blank>

Did this same or similar problem happen again after repeat use of the tobacco product?

<blank>

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

<blank>

### **Tobacco Product Parts**

### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

### **Other Tobacco Products**

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

(b) (6)

### **Attached Files**

None



### REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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

Health Problem associated with a tobacco product (not associated with

submitting? a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	   
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	<black></black>
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	<black></black>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	One Student, 2 family friends

# **Problem Summary**

Problem Start Date 12/31/2018

Problem End Date <br/>
<

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

Student began experiencing seizures on New Year's Eve and is currently being treated for such.

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

None of the above

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any

records, pictures, or other

information.

<blank>

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

4

Select Unit of Time month(s)

What is the current status of the health problem?

Not Recovered or Unresolved

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

3

**Gender** Male

Race (Select all that apply) V

White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

<blank>

Age of the person when the problem occurred

18

**Select Unit of Age** year(s)

Please list any known preexisting health problems for None the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

### What are the main symptoms or health problems?

Term describing the health problem

Seizures

### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** 

vaporizer

Select all that apply to the electronic cigarette. electronic nicotine or vaping

Uses prefilled cartridge, cart, cartomizers or carto.

product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL

When did the person purchase this product?

09/05/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

<blank>

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

### **Tobacco Product Purchase Location**

### **Tobacco Product Manufacturer Information**

### **Tobacco Product Use Details**

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	Every Day
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	8
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the problem occur?	4
Select Unit of Measure	Month(s)

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

**Tobacco Product Parts** 

### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

### **Other Tobacco Products**

### **Additional Information**

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

Young person had not experienced any seizures previous to product use.

problem. Attachments may be added on the next page.

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

(b) (6)

(max length: 50 characters)

Voluntary

Regulatory Status

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Organization Name <br/>

Confirm Email (b) (6)

First Name (b) (6

Last Name (b) (6)

Did you report the problem to the manufacturer?

Job Title <br/>
<b

Phone (b) (6)

Email (If prefilled, changing this email address will not change your Login email ID)

(b) (6)

Country United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned
Citizen Type (select all that

apply)

Concerned citizen

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

Yes

## **Problem Summary**

Problem Start Date 01/18/2018
Problem End Date 04/04/2019

**Please describe the health** I believe vape smoking is the cause of my son's seizure. There is no **problem or product problem.** history of any kind of seizures until now. He had stopped for a short

The Attachments page will accept uploads of any records, pictures, or other information.

while and the seizures had stopped and upon reuse they began again. He has been brought to the Hospital for every seizure and each time he has had an inconclusive CAT scan. He also has had 2 EEG which also came back inconclusive. We are still under the care of a neurologist. They cant seem to find the reason for these seizure. I have always suspected it was vaping related and have been very vocal about it.

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

None of the above

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

6 CAT scans and 2 EEG.

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

2

Select Unit of Time

minute(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the

problem occurred

15

Select Unit of Age

year(s)

Please list any known preexisting health problems for none1/ the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

none

## What are the main symptoms or health problems?

Term describing the health problem

Other

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the eliquid, e-juice or vape juice electronic nicotine or vaping product

for your electronic cigarette, Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Menthol

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL

When did the person purchase this product?

01/18/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

00000000000

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

batch code)

From a Friend

Do you know where the product was purchased?

No

**Manufacturer Name** 

Other

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

**Manufacturer Name (Other)** JUUL 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> **Email Address** <blank>

## **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

1

On average, how often is this tobacco product used? Every Day

Did the problem occur with first time use of the tobacco No

product?

How long has the person been using this type of tobacco product?

Select Unit of Measure	Year(s)
How soon after the tobacco product was last used did the problem occur?	6
Select Unit of Measure	Month(s)
How long has the person been using this particular brand or label?	1
Select Unit of Measure	Year(s)
Did the person continue to use this tobacco product after the problem occurred?	Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

## **Tobacco Product Parts**

## **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

## **Other Tobacco Products**

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

As a result of these seizures my son is currently under neurology care

## **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	   
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	 <blank></blank>
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	 <blank></blank>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer, Concerned citizen, Other
Describe other consumer/ concerned citizen type	PARENT
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	PARENT

## **Problem Summary**

Product Problem Type (select all that apply)

Child safety hazard, Label issue, Other

Describe the other product problem

Use of this product can cause a toxic ingestion of nicotine, seizures, and erratic heart rates.

In what setting(s) did this problem occur? (select all that apply)

Public indoor location (office, store, mall, restaurant, bar, school, sports arena)

Problem Start Date

01/04/2019

**Problem End Date** 

information.

01/28/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other

After using a nicotine vape pen, my son experienced seizures.

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

None of the above

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission, Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

2 Emergency Room visits 1 Hour EEG 24 Hour EEG Neurology Dr Visits Cardiology Dr Visits Echocardiogram 24 Hour Holter Monitor Eye Exam

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)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a

User(s)

separate report for each affected person, if possible.)

How many users were

affected?

Gender Male

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

Race (Select all that apply)

(b) (6)

White

Age of the person when the

problem occurred

16

**Select Unit of Age** year(s)

Please list any known preexisting health problems for NO PRE-EXISTING ISSUES the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

N/A

## What are the main symptoms or health problems?

Term describing the health problem

Seizures

#### **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

e-cigars, e-nookans, e-pipes, vape pens, nookan pens, and persona

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

**UNKNOWN** 

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the

Don't Know

"UL" symbol?

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

He did not purchase the product - passed around in school.

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

Unknown

How was this product acquired?

From a Friend

Do you know where the product was purchased?

No

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

## **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Some Days

Are other substances being mixed in with the tobacco product when used?

<blank>

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

<blank>

**Select Unit of Measure** 

<blank>

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

15

**Select Unit of Measure** 

Minute(s)

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

## **Other Products Used**

Has the affected person used other tobacco products No (either currently or in the past)?

#### **Other Tobacco Products**

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. This is a serious problem affecting teenagers and has completely infiltrated our school systems. The fact that these products contain toxic levels of nicotine and other dangerous chemicals when ingested is UNACCEPTABLE. I will spend thousands of dollars and countless hours on medical tests because of seizures after vaping. In addition, because of these seizures, my son's driver's license has been suspended in accordance with our state seizure laws. These products are dangerous and marketed to CHILDREN. I can provide any additional information needed in an effort to help reduce the risk of anyone else having to deal with this.

#### **Attached Files**

None



#### REPORT INFORMATION

## **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-04

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# **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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States** Street Address Line 1 Street Address Line 2 <blank> City/Town (b) (6) State **ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer apply) Are you the person who experienced health Yes problems associated with a tobacco product?

## **Problem Summary**

Problem Start Date //2016
Problem End Date //2019

**Please describe the health** I have been vaping for over 5 years but around two three years ago **problem or product problem.** I started to experience having grand mal seizures and I seen the link

The Attachments page will accept uploads of any records, pictures, or other information.

between the two and I was just wondering if that could be why I started having seizures for no reason out of the blue cuz I've never had any of my life

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

Hospitalization (overnight or longer)

**Treatment Received (select** all that apply)

Emergency Room Visit Without Hospital Admission

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

**Select Unit of Time** 

year(s)

What is the current status of the health problem?

Unknown

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

<blank>

Gender Female

**Pregnant** No

White

Race (Select all that apply)

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

26

**Select Unit of Age** 

year(s)

Please list any known preexisting health problems for the affected person

I had none then out of nowhere I started having seizures about 3 years ago when I say

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

I was taking Xanax three or four days before the seizures but the doctor told me that had nothing to do with the reason why I had the seizures and they don't know why I had them and still don't

## What are the main symptoms or health problems?

Term describing the health problem

Seizures

#### **Tobacco Products**

	Lieutionio digarette, electi
Tobacco Product Type	e-cigars, e-hookahs, e-pip

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Uses a tank or tank system, Power (watts) can be changed or adjusted, Voltage can be changed or adjusted, Button activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased for use in a capsule, tank or refillable cartridge

Describe the e-liquid mix

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine

Was the e-liquid dripped on to the atomizer or heating element?

Yes

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Vapor rising

When did the person purchase this product?

//2016

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the

No

"UL" symbol?

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

None

batch code)

What is the country of manufacture of the tobacco

**United States** 

product?

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

Yes

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location Name** Ohm vaper

Country **United States** 

**Phone** <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

Florida State

**ZIP/Postal Code** <blank>

Web Address <blank>

**Email Address** <blank>

## **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is **Every Day** this tobacco product used?

Are other substances being mixed in with the tobacco No

product when used?

Did the problem occur with first time use of the tobacco No

product?

How long has the person been using this type of

tobacco product?

5

**Select Unit of Measure** 

Year(s)

How soon after the tobacco	
product was last used did	2
the problem occur?	

Select Unit of Measure Month(s)

How long has the person been using this particular brand or label?

3

**Select Unit of Measure** Year(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

**Tobacco Product Parts** 

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

change your Login email ID)

Country United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned
Citizen Type (select all that

apply)

Consumer, Concerned citizen

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

Yes

## **Problem Summary**

Problem Start Date 02//2016

Problem End Date <br/>
<br/>
<br/>
<br/>
Plank>

**Please describe the health** I started smoking VUSE electronic cigarettes around April 2015 and I **problem or product problem.** started having seizures in February 2016 & I'm still having seizures

The Attachments page will accept uploads of any records, pictures, or other information.

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

Lasting disability or other permanent health problem

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

I'm still seeing a neurologist to try to figure out my seizures

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

<blank>

**Gender** Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

42

Select Unit of Age

year(s)

Please list any known pre-

existing health problems for the affected person

No pre-existing conditions, healthy woman

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Allergy meds, Plexus supplements

## What are the main symptoms or health problems?

Term describing the health problem

Complex partial seizures

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Select all that apply to the electronic cigarette,

**electronic nicotine or vaping** Rechargeable product **product (including electronic** 

waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

Purchased in a non-refillable disposable cartridge

electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Glycerin

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Mint (such as wintergreen or spearmint)

Was the e-liquid dripped on to the atomizer or heating element?

Yes

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

VUSE VIBE - VUSE CIRO - VUSE SOLO

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

Used the products from April 2015-November 2018

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location 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> **Email Address** <blank>

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

On average, how often is this tobacco product used? Every Day

Are other substances being mixed in with the tobacco No product when used?

Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	3
Select Unit of Measure	Year(s)
How soon after the tobacco product was last used did the problem occur?	10
Select Unit of Measure	Month(s)
How long has the person been using this particular brand or label?	3
Select Unit of Measure	Year(s)
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

# **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

### **Other Tobacco Products**

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

The only thing different in her life was smoking e-cigarettes, to cause these seizures. She's had all kinds of tests and they show no epilepsy

### **Attached Files**

None



### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside SRP)?

Yes

Describe who the problem was reported to

emergency room doctor and nurse, local.

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

**Organization Name** <blank>

**Confirm Email** 

**First Name** 

**Last Name** 

Did you report the problem No to the manufacturer?

Job Title **Phone** 

Email (If prefilled, changing this email address will not change your Login email ID)

(b) (6)

Country **United States** 

Street Address Line 1

Street Address Line 2 <blank>

City/Town

State

**ZIP/Postal Code** 

Sender Category Healthcare Professional (FdaTPR)

Healthcare Professional type Nurse Practitioner

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

<blank>

### **Problem Summary**

**Problem Start Date** 08/14/2018 **Problem End Date** 08/14/2018

Please describe the health problem or product problem. The Attachments page will accept uploads of any

My son was vaping on aug 18,2018. we were canoeing a local river here in wisconsin, when he immediately seized, and became nonresponsive. He almost drowned. It took 5 of us to restrain him and get him up the river bank to the fire/ambulance units. He remained seizing records, pictures, or other information.

and combative at Spooner Hospital ER for a couple hours. He has no recollection of what happened. I am his father, and I am a b (6). There were several RN's, paramedics and MD's on our canoe trip and we all witnessed what happened. It was seizure activity.

He would have for sure drown had we not been there. This is a healthy 18 yr old. We still dont know what happened.

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

Life threatening, Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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

5

Select Unit of Time

hour(s)

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Affected Person Identifier Code

<blank>

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

18

**Select Unit of Age** 

year(s)

Please list any known preexisting health problems for None the affected person

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

None

## What are the main symptoms or health problems?

Term describing the health problem

Prolonged seizure

#### **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype <blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

unknown vape

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the

Don't Know

"UL" symbol?

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code) <a href="https://doi.org/10.2007/journal.com/"></a>

How was this product acquired? <br/>

Manufacturer Name <br/> <br/>

## **Tobacco Product Packaging and Portions**

**Manufacturer Investigation Information** 

**Tobacco Product Purchase Location** 

**Tobacco Product Manufacturer Information** 

# **Tobacco Product Use Details**

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	Some Days
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	3
Select Unit of Measure	Weeks(s)
How soon after the tobacco product was last used did the problem occur?	2
Select Unit of Measure	Minute(s)
How long has the person been using this particular brand or label?	3
Select Unit of Measure	Month(s)
Select Unit of Measure  Did the person continue to use this tobacco product after the problem occurred?	Month(s)
Did the person continue to use this tobacco product	,

# **Tobacco Product Parts**

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

**Attached Files** 

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

(b) (6)

Regulatory Status Vo

Voluntary

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

## **Contact Information - Sender**

Organization Name	(b) (6)
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	(b) (6)
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	 blank>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer
Are you the person who experienced health	Yes

Yes

# **Problem Summary**

problems associated with a

tobacco product?

 Problem Start Date
 04/03/2019

 Problem End Date
 04/03/2019

**Please describe the health** on april 3rd i was in the tanning bed and got out and was really really **problem or product problem.** hot so i went to the bathroom and was twitching loss of eye sight loss

The Attachments page will accept uploads of any records, pictures, or other information.

of hearing and fell on the floor and my arms and legs twitched and i couldnt see or hear anything and lost control of my body and blacked out and dont remember how long that lasted for. I had hit the juul right before i went into the tanning bed, i hit it all the time. then i regained control of my eye sight and hearing after about 10-15 minuets of sweating and almost vomitting and could stand, then walked out.

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

None of the above

Treatment Received (select all that apply)

Self-Treated

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

I just drank water and was fine after. just a little dizzy

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

15

Select Unit of Time

minute(s)

What is the current status of the health problem?

Recovered or Resolved

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Female
Pregnant <br/>
Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

23

**Select Unit of Age** 

year(s)

Please list any known preexisting health problems for the affected person

No existing health problems besides Asthma

### **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Albuteral inhalor

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto.

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Mint (such as wintergreen or spearmint)

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL

When did the person purchase this product?

04/03/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

Yes

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

Purchase Location Name WaWa

**Country** United States

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

City/Town <br/>
State <br/>
ZIP/Postal Code <br/>
<br/

Web Address <br/> <br/>

Email Address <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

### **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	Yes
How long has the person been using this type of tobacco product?	<blank></blank>
Select Unit of Measure	<blank></blank>
How soon after the tobacco product was last used did the problem occur?	5
Select Unit of Measure	Minute(s)
How long has the person been using this particular brand or label?	<black></black>
Select Unit of Measure	<blank></blank>
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	No
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

# **Other Products Used**

# **Other Tobacco Products**

# **Additional Information**

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Did you report the problem to the manufacturer?

Job Title <br/>
Phone <br/>
<b

Email (If prefilled, changing this email address will not change your Login email ID)

<blank>

Country <br/>
Street Address Line 1 <br/>
Street Address Line 2 <br/>
City/Town <br/>
<br/

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that apply)

<blank>

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

<blank>

## **Problem Summary**

Please describe the health problem or product problem.

Child had multiple epileptic seizures within a 48 hour period.

The Attachments page will accept uploads of any records, pictures, or other information.

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

Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Eeg showed seizure activity in the left frontal lobe. No significant abnormalities in brain scan MRI. Child now taking anti-seizure medication: Keppra

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

<blank>

**Select Unit of Time** 

<blank>

What is the current status of the health problem?

Not Recovered or Unresolved

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

<blank>

affected?

Gender

Male

Race (Select all that apply)

White

**Ethnicity** 

Not Hispanic or Latino

Birth date of the person who experienced the problem

//2004

Age of the person when the

problem occurred

14

Select Unit of Age

year(s)

Please list any known preexisting health problems for <blank>

the affected person

### **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Lexipro

## What are the main symptoms or health problems?

Term describing the health problem

**Epilepsy** 

### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** <blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

SMOK brand badge style

When did the person purchase this product?

<blank>

**UNIVERSAL PRODUCT** CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol? <a href="https://doi.org/10.1001/journal.org/">blank></a>

Any other identifying tobacco product codes (for example, SKU, item/catalog <br/>number, manufacturing date/ batch code) <br/>

How was this product acquired? <br/>

Do you know where the product was purchased? <black</pre>

Manufacturer Name <br/> <br/>

## **Tobacco Product Packaging and Portions**

**Manufacturer Investigation Information** 

**Tobacco Product Purchase Location** 

**Tobacco Product Manufacturer Information** 

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

<blank>

**Select Unit of Measure** 

Month(s)

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

<blank>

**Select Unit of Measure** 

Minute(s)

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

**Attached Files** 

None



### REPORT INFORMATION

### **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-04

FDA ICSR ID (b) (6)

Followup by using your

account



Proxy Report Information (not applicable if this is not a proxy report)

# **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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	<black></black>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	 <blank></blank>
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	 <blank></blank>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Mother

# **Problem Summary**

Problem Start Date 04/26/2018

Problem End Date <br/>
<

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

My son has had 2 seizures in the past year. It was determined from his Pediatric Neurologists that it is from Vaping. Both times he had a seizure he had just vaped. The hospital ran series of tests, MRI, EEG, EKG, etc. No Epileptic symptoms. This really needs to be investigated. I'm willing to give ANY information you need.

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

None of the above

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

On April 26, 2018 after his seizure, we went to the ER where they ran a series of tests. Cardiac Monitor, CBC, Metabolic Panel, Drug screen, Prolactin Blood test, Urinalysis, CT of Head, EKG, Xray of chest. We were then referred to a pediatric neurologists where they performed an EEG. All tests were conclusive there was a seizure, but there were no underlying Epileptic diagnosis.

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

3

Select Unit of Time hour(s)

What is the current status of the health problem?

Recovered or Resolved

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

**Gender** Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

15

Select Unit of Age year(s)

Please list any known preexisting health problems for the affected person

No pre-existing health problems.

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

NA

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

### **Tobacco Products**

Tobacco Product Type

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Puff/flow activated

product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Tobacco, Menthol, Mint (such as wintergreen or spearmint), Fruit, Candy or Chocolate, Combination/mixture of flavors

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

//2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

### **Tobacco Product Purchase Location**

### **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	Rarely
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	2
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the problem occur?	1
Select Unit of Measure	Second(s)

How long has the person been using this particular brand or label?

2

**Select Unit of Measure** 

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products No (either currently or in the past)?

### **Other Tobacco Products**

### **Additional Information**

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

This should be investigated. Glad this report came out.

problem. Attachments may be added on the next page.

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

(b) (6)

Regulatory Status V

Voluntary

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside <br/>
SRP)?

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

**Organization Name** <blank> **Confirm Email First Name** (b) (6) **Last Name** Did you report the problem No to the manufacturer? **Job Title** <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States Street Address Line 1** Street Address Line 2 <blank> City/Town **State ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer, Concerned citizen apply) Are you the person who experienced health Yes problems associated with a tobacco product?

## **Problem Summary**

Product Problem Type (select all that apply)

<blank>

In what setting(s) did this problem occur? (select all that apply)

<blank>

**Problem Start Date** 

09/24/2018

**Problem End Date** 

10/05/2018

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information. After using a Juul vape for about 8 months, I had a huge siezure at a friends house where I had fallen from standing in the kitchen and hit my head 3 times on the way down, I remember waking up confused of why I was laying in the floor, it felt like I was just waking up from a nap. (I've never experienced seizures ever before) after I woke up and sat up I guess I had another seizure according to my friend and I remember waking up once more. Then after that not knowing what was wrong my father rushed me to the hospital where I had dangerously low blood pressure and was admitted to the hospital to do a bunch of tests and to monitor me. Even after all the tests that they had done, no one could find anything wrong, and they sent me home like nothing was wrong, which was the scariest part, I had just had a huge siezure and I don't know why. After that incident, about 3-4 days later I had another seizure in the shower, where I found myself on the floor of the shower with the water running, confused of why I was on the floor again and also had hit my head again, i never told anyone about the second incident because I drive race cars full time, and was in fear that I might not be able to do what I do anymore. I no longer vape and have not had any experiences like that since I stopped vaping.

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

Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Was treated in the emergency room, and admitted overnight for testing, no problems could be found.

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

2

**Select Unit of Time** 

week(s)

What is the current status of the health problem?

Unknown

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a

User(s)

separate report for each affected person, if possible.)

How many users were

affected?

Gender Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the

problem occurred

23

Select Unit of Age year(s)

Please list any known preexisting health problems for None the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

## What are the main symptoms or health problems?

Term describing the health problem

Seizures

#### **Tobacco Products**

manufacture of the tobacco

product?

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice) E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** vaporizer Select all that apply to the electronic cigarette, Disposable (non-refillable) product, Rechargeable product, Uses electronic nicotine or vaping prefilled cartridge, cart, cartomizers or carto., Puff/flow activated product (including electronic waterpipe) Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, <blank> electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the Nicotine following? (select all that apply) Was the e-liquid dripped on to the atomizer or heating Unknown element? Full Tobacco Product Name, including Brand and Sub-JUUL Brand (if unknown, please enter "unknown") When did the person 09/01/2018 purchase this product? **UNIVERSAL PRODUCT** <blank> CODE (UPC) from Label Does the involved product device or package bear the Don't Know "UL" symbol? Any other identifying tobacco product codes (for example, SKU, item/catalog <blank> number, manufacturing date/ batch code) What is the country of

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location 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> **Email Address** <blank>

## **Tobacco Product Manufacturer Information**

# **Tobacco Product Use Details**

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	Every Day
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	8
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the problem occur?	10
Select Unit of Measure	Minute(s)
How long has the person been using this particular brand or label?	8
Select Unit of Measure	Month(s)
Did the person continue to use this tobacco product after the problem occurred?	No
Did this same or similar problem happen again after repeat use of the tobacco product?	N/A - Person did not restart use
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

**Tobacco Product Type** Other

Description of other tobacco

product type

Nicotine pouches

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please

enter "unknown")

Zyn

Is the tobacco product currently being used?

Yes

How is the tobacco product

used?

Placed, rubbed, or swished in mouth

On average, how often is the tobacco product used?

**Every Day** 

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

I have not had any problems since I stopped vaping and started using nicotine pouches.

#### **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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

Health Problem associated with a tobacco product (not associated with

submitting? a product problem or defect)

Did you report this problem somewhere else (outside SRP)?

Yes

Describe who the problem was reported to

Vanderbilt University Children's hospital

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

**Organization Name Confirm Email First Name Last Name** Did you report the problem Yes to the manufacturer? **Job Title Phone** <blank> Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States Street Address Line 1** Street Address Line 2 <blank> City/Town **State ZIP/Postal Code Sender Category** Healthcare Professional (FdaTPR) Healthcare Professional type Other Public Health Professional Are you the person who experienced health No problems associated with a tobacco product? Describe your relationship to the person who mother experienced the health problem

### **Problem Summary**

Problem Start Date 02/28/2019

Problem End Date

04/03/2019

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

5 instances of black outs with seizure activity including vomiting, severe headache, blurred vision and hearing loss.

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

Other serious medical event

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

All normal level blood work, CT scan, EKG and EEG results normal.

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

**Select Unit of Time** 

month(s)

What is the current status of the health problem?

Unknown

## **Affected Person**

Affected Person Identifier Code

14 year old female

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

14

**Select Unit of Age** year(s)

Please list any known preexisting health problems for none the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications. vitamins, and/or supplements taken around the time of the health problem.

none

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

## **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Disposable (non-refillable) product, Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto.

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL

When did the person purchase this product?

01/31/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

JUUL

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product acquired?

From a Friend

Do you know where the product was purchased?

No

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

6

**Select Unit of Measure** Month(s)

How soon after the tobacco product was last used did 20 the problem occur?

**Select Unit of Measure** Minute(s)

How long has the person been using this particular brand or label?

6

**Select Unit of Measure** Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

No

#### **Tobacco Product Parts**

**Full Tobacco Product Part** Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL

**Tobacco Product Part Type** Cartridge

When was this tobacco product part purchased or acquired?

01/31/2019

**UNIVERSAL PRODUCT** CODE (UPC) from Label

<blank>

Any other identifying tobacco product part codes(e.g. SKU, item/catalog number)

<blank>

What is the country of manufacture of the tobacco <blank> product part?

Where is the tobacco product part now?

<blank>

Do you know who manufactured this tobacco product part?

No

#### **Tobacco Product Part Purchase Location**

How was this tobacco product part acquired? From a Friend

Purchase Location Name (b) (6)

**Country** United States

Phone <br/> <blank>

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code (b) (6)

Web Address <br/>
Email Address <br/>
<br/

## **Tobacco Product Part Manufacturer Information**

State <br/> <br/>

State/Province <blank>

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

Several girls in middle school and high school have reported blacking out and seizure activity after using the JUUL

### **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

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

Sender Category Consumer/Concerned Citizen (FdaTPR)

## **Problem Summary**

**Product Problem Type** (select all that apply)

Other

Describe the other product problem

Vaping and died from a sudden unexplained death from seizure

In what setting(s) did this problem occur? (select all that apply)

One person using one or more product(s), In the place where I live

**Problem Start Date** 06/02/2015 **Problem End Date** 06/20/2015

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

My email is (b) (6)

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

Death

**Reported Cause of Death** 

Seizure

**Treatment Received (select** all that apply)

None

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a

User(s)

separate report for each affected person, if possible.)

How many users were

affected?

Female Gender

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the

problem occurred

the affected person

25

Select Unit of Age year(s)

Please list any known pre-

existing health problems for Polyglandular autoimmune disease type 2

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health

problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Prolonged epileptic seizure

# **Tobacco Products**

Tobacco Product Type	Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)
Tobacco Product Subtype	E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer
Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)	Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Uses a tank or tank system, Button activated
Select all that apply to the e- liquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product	Purchased for use in a capsule, tank or refillable cartridge
Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)	Nicotine, Flavor(s)
What type(s) of flavor(s) does the e-liquid contain? (select all that apply)	Candy or Chocolate, Combination/mixture of flavors
Was the e-liquid dripped on to the atomizer or heating element?	Yes
Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")	Unknown
When did the person purchase this product?	07/01/2015
UNIVERSAL PRODUCT CODE (UPC) from Label	<black></black>
Does the involved product device or package bear the "UL" symbol?	Don't Know
Any other identifying tobacco product codes (for example, SKU, item/catalog	                            

number, manufacturing date/batch code)

What is the country of

manufacture of the tobacco United States

product?

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

<blank>

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

## **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco product?

No

How long has the person been using this type of tobacco product?

6

**Select Unit of Measure** 

Month(s)

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

5

**Select Unit of Measure** 

Day(s)

How long has the person been using this particular brand or label?

6

**Select Unit of Measure** 

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

Unknown

### **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products

(either currently or in the past)?

### **Other Tobacco Products**

**Tobacco Product Type** Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

U known

Is the tobacco product currently being used?

No

## **Additional Information**

## **Attached Files**

None



#### REPORT INFORMATION

## **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-04

FDA ICSR ID (b) (6)

Followup by using your

account

(b) (6)

# Proxy Report Information (not applicable if this is not a proxy report)

# **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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem <blank> to the manufacturer? Job Title **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States Street Address Line 1** Street Address Line 2 <blank> City/Town **State ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer, Concerned citizen apply)

Yes

## **Problem Summary**

problems associated with a

Are you the person who experienced health

tobacco product?

 Problem Start Date
 09/15/2018

 Problem End Date
 09/15/2018

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

In the past three years I have had two seizures. I have never had seizures prior to this time and the only major difference in my life is that I started vaping only instead of smoking or smoking and vaping.

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

None of the above

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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

<blank>

**Select Unit of Time** 

<blank>

What is the current status of the health problem?

Unknown

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

44

Select Unit of Age

year(s)

Please list any known preexisting health problems for <br/>blank> the affected person

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Seizures

#### **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype <blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Vaping liquid and vape "mod"

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the

<blank>

"UL" symbol?

Any other identifying tobacco product codes (for example, SKU, item/catalog < number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco

**United States** 

product?

Where is the tobacco product now?

Unknown

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

## **Tobacco Product Purchase Location**

**Purchase Location 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>

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

On average, how often is this tobacco product used? Every Day

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco product?

No

How long has the person been using this type of tobacco product?

3

Select Unit of Measure Year(s)

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

1

Select Unit of Measure

Hour(s)

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

**Tobacco Product Type** Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Is the tobacco product currently being used?

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. My first seizure happened approximately two years ago and my second was in September of 2018. Prior to the first one, I had not had a seizure before. In both instances, I have been checked to see if there is an underlying cause and none have been found. I did research to see if there was a correlation between vaping and seizures as that was the only major change I had in my life. I did not find anything to confirm my curiosity so I did not stop vaping.

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> **Phone** Email (If prefilled, changing this email address will not change your Login email ID) Country **United States** Street Address Line 1 <blank> Street Address Line 2 <blank> City/Town <blank> State <blank> **ZIP/Postal Code** <blank> **Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer apply) Are you the person

Yes

# **Problem Summary**

who experienced health

tobacco product?

problems associated with a

Please describe the health problem or product problem. Seizures after vaping

The Attachments page will accept uploads of any records, pictures, or other information.

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

Lasting disability or other permanent health problem, Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Receiving treatment for seizures 2 months later. 5 day hospitalization.

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

Select Unit of Age year(s)

Please list any known preexisting health problems for <br/>blank> the affected person

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

33

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

### **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Disposable (non-refillable) product, Rechargeable product, Button

activated, Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the Other following? (select all that apply) Describe other e-liquid Cannabis ingredients Was the e-liquid dripped on to the atomizer or heating Unknown element? Full Tobacco Product Name, including Brand and Sub-Unknown Brand (if unknown, please enter "unknown") When did the person 12/03/2018 purchase this product? UNIVERSAL PRODUCT <blank> CODE (UPC) from Label Does the involved product device or package bear the Don't Know "UL" symbol? Any other identifying tobacco product codes (for example, SKU, item/catalog <blank> number, manufacturing date/ batch code) What is the country of manufacture of the tobacco <blank> product? Where is the tobacco <blank> product now? How was this product <blank> acquired?

Do you know where the

Manufacturer Name

product was purchased?

## **Tobacco Product Packaging and Portions**

<blank>

# **Manufacturer Investigation Information**

# **Tobacco Product Purchase Location**

# **Tobacco Product Manufacturer Information**

# **Tobacco Product Use Details**

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	Rarely
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	<blank></blank>
Select Unit of Measure	<black></black>
How soon after the tobacco product was last used did the problem occur?	<blank></blank>
Select Unit of Measure	<black></black>
How long has the person been using this particular brand or label?	<black></black>
Select Unit of Measure	<black></black>

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? **Job Title** <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States Street Address Line 1** Street Address Line 2 <blank> City/Town **State ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer apply) Are you the person who experienced health Yes problems associated with a

# **Problem Summary**

tobacco product?

Problem Start Date 02/08/2018

Problem End Date <br/>
<

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

I had a seizure on 2/8/18. I had been a recent user of the product Juul. I had another seizure on March 4, 2019 after continuing to use the product.

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

None of the above

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

I have had MRI's, CT Scan, Blood Tests, EKG, EEG.

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)

What is the current status of the health problem?

Not Recovered or Unresolved

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

21

Select Unit of Age

year(s)

Please list any known preexisting health problems for None the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

## What are the main symptoms or health problems?

Term describing the health problem

Other

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, product (including electronic waterpipe)

**electronic nicotine or vaping** Uses prefilled cartridge, cart, cartomizers or carto.

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Coloring Agents, Flavor(s), Glycerin, Propylene Glycol

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Mint (such as wintergreen or spearmint)

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL

When did the person purchase this product?

01/01/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

<blank>

Manufacturer Name

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

On average, how often is this tobacco product used? Every Day

Are other substances being mixed in with the tobacco No

mixed in with the tobacco product when used?

Did the problem occur with first time use of the tobacco No

product?

How long has the person been using this type of

tobacco product?

Select Unit of Measure Month(s)

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

<blank>

Select Unit of Measure Hour(s)

How long has the person been using this particular brand or label?

6

**Select Unit of Measure** 

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

Full Tobacco Product Part Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

**Tobacco Product Part Type** 

Cartridge

When was this tobacco product part purchased or acquired?

02/01/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Any other identifying tobacco product part codes(e.g. SKU, item/catalog

<blank>

number)

What is the country of manufacture of the tobacco

**United States** 

product part?

Where is the tobacco product part now?

Product was discarded

Do you know who manufactured this tobacco

Yes

product part?

### **Tobacco Product Part Purchase Location**

How was this tobacco product part acquired?

Purchase Location Name <blank>

**Country** United States

**Phone** <blank> **Street Address Line 1** <blank> **Street Address Line 2** <blank> City/Town <blank> State <blank> **ZIP/Postal Code** <blank> Web Address <blank> **Email Address** <blank>

### **Tobacco Product Part Manufacturer Information**

Manufacturer Name<blank>State<blank>State/Province<blank>

### **Other Products Used**

## **Other Tobacco Products**

# **Additional Information**

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country <blank> Street Address Line 1 Street Address Line 2 <blank> City/Town (b) (6) **State ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer apply) Are you the person who experienced health Yes

# **Problem Summary**

problems associated with a

tobacco product?

Product Problem Type (select all that apply)

Label issue

Describe the other product problem

In what setting(s) did this problem occur? (select all

that apply)

In the place where I live

**Problem Start Date** 

<blank>

**Problem End Date** 

<blank>

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other

Seizures

information.

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

Lasting disability or other permanent health problem

**Treatment Received (select** 

all that apply)

Self-Treated

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

The Attachments page will accept uploads of any records, pictures, or other information.

Sleeping

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

<blank>

**Select Unit of Time** 

<blank>

What is the current status of the health problem?

<blank>

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

Both

How many users were affected?

1

How many nonusers were

affected?

Gender Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the

problem occurred

43

**Select Unit of Age** year(s)

Please list any known preexisting health problems for None the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

# What are the main symptoms or health problems?

Term describing the health problem

Other

## **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Uses a tank or tank system, Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge, Purchased for use in a capsule, tank or refillable cartridge, Mixed in a shop or on-line per request or "to order", Mixed or modified by the user

Describe the e-liquid mix

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Tobacco, Menthol, Mint (such as wintergreen or spearmint), Clove or Spice, Fruit, Candy or Chocolate, Alcoholic Drink, Combination/mixture of flavors. Other

Describe other e-liquid flavor(s)

<blank>

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Unable to remember

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

Nο

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

# **Tobacco Product Manufacturer Information**

### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	7
Select Unit of Measure	Year(s)
How soon after the tobacco product was last used did the problem occur?	6
Select Unit of Measure	Week(s)
How long has the person been using this particular brand or label?	7
Select Unit of Measure	Year(s)
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

# **Other Products Used**

# **Other Tobacco Products**

# **Additional Information**

# **Attached Files**

None



### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

**Regulatory Status** Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Organization Name <br/> <br/>

Confirm Email (b) (6)

First Name (b) (6)

Last Name (b) (6)

Did you report the problem to the manufacturer?

Job Title <br/> <blank><br/> <blank>

Email (If prefilled, changing this email address will not change your Login email ID)

b) (6)

**Country** United States

Street Address Line 1 <blank>
Street Address Line 2 <blank>
City/Town <br/>
<b

State <br/> <br/>

ZIP/Postal Code <br/> <b

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that Consumer

apply)

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

Yes

# **Problem Summary**

Problem Start Date 02//2017
Problem End Date 02//2017

Please describe the health problem or product problem. Had sei

Had seizures after using ecig

The Attachments page will accept uploads of any records, pictures, or other information.

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

Lasting disability or other permanent health problem, Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Healthcare Professional Visit, Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Overnight stay in hospital, ct scan, MRI, eeg, blood work

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Female

**Pregnant** No

Race (Select all that apply) American Indian or Alaskan Native, White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

27

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

<blank>

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Uses a tank or tank system, Power (watts) can be changed or adjusted, Voltage can be changed or adjusted, Button activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

Purchased for use in a capsule, tank or refillable cartridge

electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Coloring Agents, Flavor(s), Glycerin, Propylene Glycol

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Menthol, Fruit, Candy or Chocolate, Combination/mixture of flavors

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown.

When did the person purchase this product?

07//2016

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product acquired?

In a Store

Do you know where the product was purchased?

Yes

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

Purchase Location Name Cigs 4 Less

**Country** United States

Phone <br/> <blank>

Street Address Line 1 <br/>
<b

Street Address Line 2 <blank>

City/Town Duluth

**State** Minnesota

ZIP/Postal Code <br/> <b

Web Address <br/> <blank>

Email Address <br/> <blank>

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

2

Select Unit of Measure Year(s)

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

7

Select Unit of Measure Month(s)

How long has the person been using this particular brand or label?

2

Select Unit of Measure Year(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

### **Tobacco Product Parts**

## **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

**Tobacco Product Type** Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Marlboro menthols

Is the tobacco product currently being used?

No

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

Saw the news said to send this in if I had seizures after using an ecig

#### **Attached Files**

None



#### REPORT INFORMATION

#### **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-04

FDA ICSR ID

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

## **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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

## **Contact Information - Sender**

Organization Name	 <blank></blank>
Confirm Email	(b) (6)
First Name	
Last Name	(b) (6)
Did you report the problem to the manufacturer?	   
Job Title	   
Phone	
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer
Are you the person who experienced health problems associated with a tobacco product?	<black></black>

# **Problem Summary**

Problem Start Date 12/04/2018

Problem End Date <br/>
<

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Started having seizures after vaping high level nicotine Juul pods trying to quit smoking, have since been diagnosed with epilepsy and i am still having seizures from this.

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

Lasting disability or other permanent health problem, Life threatening, Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

had an MRI, a 3 day EEG test done, have been perscirbed Keppra, full blood work. and have been diagnosed with Epilepsy

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

<blank>

**Select Unit of Time** 

<blank>

What is the current status of the health problem?

<blank>

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

1

affected?

Gender

Male

Race (Select all that apply)

<blank>

**Ethnicity** 

Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

27

Select Unit of Age

year(s)

Please list any known preexisting health problems for Asthma the affected person

#### **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

none

#### What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, product (including electronic by the user), Puff/flow activated waterpipe)

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or electronic nicotine or vaping carto., Uses refillable cartridge, cart, cartomizers or carto (that are filled

liquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product	Purchased for use in a capsule, tank or refillable cartridge
Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)	Nicotine, Flavor(s), Propylene Glycol
What type(s) of flavor(s) does the e-liquid contain? (select all that apply)	Fruit, Candy or Chocolate, Combination/mixture of flavors
Was the e-liquid dripped on to the atomizer or heating element?	No
Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")	Juul, Juul Pods, and ZPods. Mr Salty and Naked 100 Juices
When did the person purchase this product?	10/01/2018
UNIVERSAL PRODUCT CODE (UPC) from Label	          
Does the involved product device or package bear the "UL" symbol?	<black></black>
Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)	   
What is the country of manufacture of the tobacco product?	<black></black>
Where is the tobacco product now?	   
How was this product acquired?	   
Do you know where the product was purchased?	<black></black>
Manufacturer Name	   

Select all that apply to the e-

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

### **Tobacco Product Use Details**

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	<black></black>
Are other substances being mixed in with the tobacco product when used?	<blank></blank>
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	1
Select Unit of Measure	Year(s)
How soon after the tobacco product was last used did the problem occur?	9
Select Unit of Measure	Month(s)

How long has the person been using this particular brand or label?

1

**Select Unit of Measure** 

Year(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

**Tobacco Product Type** 

Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Marlboro Light Special Blend

Is the tobacco product currently being used?

No

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

Have been having seizures even after not vaping and while vaping seems to be a permanent issue, that i now have to deal with because i thought i was making a healthier choice.

#### **Attached Files**

None



#### REPORT INFORMATION

#### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## 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?

a product problem or defect)

Health Problem associated with a tobacco product (not associated with

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	   
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	<black></black>
Phone	
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	<black></black>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	my 16 year old son

# **Problem Summary**

Problem Start Date 01/30/2018

Problem End Date 01/21/2019

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

My son had 5 seizures that were all associated with vaping tobacco

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

Life threatening, Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

He had three emergency room visits 2 MRI's 2 cat scans multiple blood tests 2 month stay in an inpatient unit for nicotine addition He had to leave public high school and go to a private boarding school to protect him from vaping

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

u. .

What is the current status of the health problem?

Select Unit of Time

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

year(s)

How many users were

affected?

1

Gender Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

15

**Select Unit of Age** year(s)

Please list any known preexisting health problems for the affected person

cleft palate ADHD anxiety

#### **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

concerta Lexapro intuiniv

#### What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** 

vaporizer

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or Select all that apply to the electronic cigarette. carto., Uses refillable cartridge, cart, cartomizers or carto (that are filled **electronic nicotine or vaping** by the user)

product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Mixed in a shop or on-line per request or "to order"

Describe the e-liquid mix

JUUL high nicotine

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Mint (such as wintergreen or spearmint), Fruit, Candy or Chocolate

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL

When did the person purchase this product?

01/24/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product acquired?

In a Store

Do you know where the product was purchased?

Yes

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location 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> **Email Address** <blank>

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?	Every Day
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	1
Select Unit of Measure	Year(s)
How soon after the tobacco product was last used did the problem occur?	1
Select Unit of Measure	Month(s)
How long has the person been using this particular brand or label?	1
Select Unit of Measure	Year(s)
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

My son purchased JUUL and other vaping products on line and in a vaping store in Media PA. No one is checking ID.

#### **Attached Files**

None

Receipt No: RCT(b) (6) FDA 3500B Form

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 (D) (Department: CTP | RCT No.: RCT-(D) (E) | CTU Triage Date: 04-04-2019 | Total Pages: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			District Co.
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		1
Override Auto Calculation Rule	No		2.000
FDA Received Date	03-Apr-2019	CTU Received Date	03-Apr-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

ontact			September 1	
ase eporter	First Name	Last Name	Email Address	Phone
3	(b) (6)	(b) (6)	(b) (6)	
ction A	- About the Problem			
	nd of problem was it? all that apply)	Used a product incorrectly w	effect (including new or worsening sympton hich could have or led to a problem uality of the product g from one product maker to another maker	
Date the	e problem occurred	05-Aug-2016		
Serious		Yes		
(Check	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important med	The state of the s	
	erious/important medical (Please Describe Below)	Had a seizure		
ell us w y additio	hat happened and ho	w it happened (Include a	s many details as possible FI	DA may reach out to you f
epilepsy and end	and never had a seizure	before then and haven't had with heart palpitations, and	neurologist and she confirmed that d another one. Also, recently I chat blood pressure issues. I stopped	nged flavors on my vape juice

levant Test/Laboratory	Data		1 of 1
Test Name	EEG	Test Date	24-Aug-2016
Test Result	Seizure	Test Unit	
Low Test Range		High Test Range	

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 10 (6) | Department: CTP | RCT No.: RCT-(5) (6) | GTU Triage Date: 04-04-2019 | Total Pages;
5

More Information Available?				
Additional Comments				
Section B - Product Availability				
Do you still have the product in case we need to evaluate it?	Yes			
Do you have a picture of the product? (check yes if you are including a picture)	No			
Section C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Cosmetic, Dietary Suppler	nent or Food/Medicina	al Food	
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Vape			
Name of the company that makes (or compounds) the product				
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmace Generic Biosimilar	y or an Outsourcing Facility	(	
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
Did the problem return if the person started taking or using the product again?	Yes			
Drug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used	Respiratory (inhalation)	If Other		
Date the person first started taking or using the product			1	
Date the person stopped taking	-			

Generated by: SYSTEM Generated on: 03-Apr-2019 23:45:38 Page 2 of 5 Receipt No: RCT-(b) (6) FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-00 (6) | Department: CTP | RCT No.: RCT-00 (6) | CTU Triage Date: 04-04-2019 | Total Pages:

	Give best estimate of duration		Tel
	Is therapy still on-going?		H
W	The receipt to the second representation of t	oduct? (such as what condition was it supposed to treat) 1 of 1	
	To help quit smoking		
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Oi	ther identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	or implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
D	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	o Had the Problem	
	Person's Initials	W 151	
	Gender	Female	1
	Age (specify unit of time for age)		
	Date of Birth	(b) (6)	m
	Weight	47.25 kg	
	Ethnicity (Choose only one)		
	Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

Please list all allergies (suc	ch as to drugs, foods, pollen or others)	
	formation about the person (such as smoking, pregnanc	y, alcohol use, etc.)
Smoker		
	medications and medical devices being used	(3)
atenolol 25mg		
List all over-the-counter me	edications and any vitamins, minerals, supplements, and	l herbal remedies being used.
Women's one a day vitami		
Section F - About the Pers	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		75
Title		
Last name	(b) (6)	i D
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	000	7 11
Country		
ZIP or Postal code	USA	) [b]
	USA (b) (6)	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	- 17.72	)   10.1 
Telephone number Email address	- 17.72	

Generated by: SYSTEM Generated on: 03-Apr-2019 23:45:38 Page 4 of 5

Reporter Organization

Reporter Speciality

Department

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (0) | Department: CTP | RCT No.; RCT-(0) (6) | CTU Triage Date: 04-04-2019 | Total Pages;
5

Today's date	03-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM 03-Apr-2019 23:45:38 Page 5 of 5 Generated on:



#### REPORT INFORMATION

#### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Organization Name <br/> <br/>

Confirm Email <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

First Name (b) (6)

Last Name (b) (6

Did you report the problem to the manufacturer?

Job Title <br/>
Phone <br/>
<b

Email (If prefilled, changing this email address will not change your Login email ID)

<blank>

Country <br/> <blank>

Street Address Line 1 <br/> <b

Street Address Line 2 <blank>

City/Town <br/> <blank>

State <br/> <br/>

ZIP/Postal Code <br/> <b

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that Consumer

apply)

Are you the person who experienced health problems associated with a

tobacco product?

Yes

## **Problem Summary**

Problem Start Date <br/> <br/>

Problem End Date <br/> <

**Please describe the health** After smoking excess amount of tobacco products I would fall **problem or product problem.** unconscious and have a seizure

The Attachments page will accept uploads of any records, pictures, or other information.

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

<blank>

Treatment Received (select all that apply)

Self-Treated

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

<blank>

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

Select Unit of Age year(s)

Please list any known preexisting health problems for <blank> the affected person

#### **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

21

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

**Tobacco Product Type** Roll-your-own cigarette

<blank> **Tobacco Product Subtype** 

**Full Tobacco Product Name**, including Brand and Sub-Brand (if unknown, please enter "unknown")

Bugler's

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco <blank> product?

Where is the tobacco product now?

<blank>

How was this product acquired?

In a Store

Do you know where the product was purchased?

<blank>

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

**Manufacturer Investigation Information** 

**Tobacco Product Purchase Location** 

**Tobacco Product Manufacturer Information** 

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

Yes

Describe what substances are being mixed with the tobacco product

Marijuana

Did the problem occur with first time use of the tobacco product?

No

How long has the person been using this type of tobacco product?

1

Select Unit of Measure

Year(s)

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

<blank>

Select Unit of Measure

<blank>

How long has the person been using this particular brand or label?

<black>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

No

#### **Tobacco Product Parts**

Full Tobacco Product Part Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

**Tobacco Product Part Type** 

Tobacco

When was this tobacco product part purchased or acquired?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Any other identifying tobacco product part codes(e.g. SKU, item/catalog number)

<blank>

What is the country of manufacture of the tobacco

<blank>

product part?

\Diaiik\*

Where is the tobacco product part now?

<blank>

Do you know who manufactured this tobacco

<blank>

product part?

#### **Tobacco Product Part Purchase Location**

How was this tobacco product part acquired?

<blank>

**Purchase Location Name** 

<blank>

Country

<blank>

Phone

<blank>

Street Address Line 1

<blank>

**Street Address Line 2** 

<blank>

City/Town

<blank>

State

دامام ما ما

**ZIP/Postal Code** 

<blank>

Web Address <br/>
Email Address <br/>
<br/

#### **Tobacco Product Part Manufacturer Information**

State <br/> <br/>

State/Province <blank>

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Select all that apply to
the electronic cigarette,
electronic nicotine or vaping
product (including electronic

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or
carto., Uses refillable cartridge, cart, cartomizers or carto (that are filled
by the user), Uses a tank or tank system, Modified: the original product
was modified, Power (watts) can be changed or adjusted, Voltage can

be changed or adjusted, Button activated

How has the electronic cigarette, electronic nicotine or vaping product been The tank syst

modified by the user? (select all that apply)

The tank system has been changed

Select all that apply to the eliquid, e-juice or vape juice

electronic nicotine or vaping

product

waterpipe)

for your electronic cigarette, Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit, Candy or Chocolate

Was the e-liquid dripped on to the atomizer or heating element?	Yes
Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")	Unknown
When did the person purchase this product?	<black></black>
UNIVERSAL PRODUCT CODE (UPC) from Label	<blank></blank>
Does the involved product device or package bear the "UL" symbol?	<black></black>
Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)	<blau></blau>
What is the country of manufacture of the tobacco product?	<blank></blank>
Where is the tobacco product now?	<blank></blank>
How was this product acquired?	<blank></blank>
Do you know where the product was purchased?	<blank></blank>
Manufacturer Name	<blank></blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is **Every Day** this tobacco product used?

Are other substances being mixed in with the tobacco No product when used?

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

4

**Select Unit of Measure** 

Year(s)

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

<blank>

**Select Unit of Measure** 

<blank>

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

Full Tobacco Product Part Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

**Tobacco Product Part Type** 

Battery(reusable)

When was this tobacco product part purchased or acquired?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Any other identifying tobacco product part codes(e.g. SKU, item/catalog

<blank>

number)

What is the country of manufacture of the tobacco product part?

<blank>

Where is the tobacco product part now?

<blank>

Do you know who manufactured this tobacco product part?

<blank>

# **Tobacco Product Part Purchase Location**

How was this tobacco product part acquired?

<blank>

**Purchase Location 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>
Email Address <blank>

## **Tobacco Product Part Manufacturer Information**

State <br/>
State/Province <br/>
<br

# **Other Products Used**

#### **Other Tobacco Products**

#### **Additional Information**

## **Attached Files**

None



#### REPORT INFORMATION

## **Report Profile**

FPSR.FDA.CTP.V.V3 **Report Version** 

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID

Report Key for Followup

# Proxy Report Information (not applicable if this is not a proxy report)

# **Report Identifying Information**

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

**Regulatory Status** Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email** <blank> **First Name** <blank> <blank> **Last Name** 

Did you report the problem to the manufacturer?

No

**Job Title** <blank> **Phone** <blank>

Email (If prefilled, changing this email address will not change your Login email ID)

<blank>

Country **United States** 

Street Address Line 1 <blank> Street Address Line 2 <blank> City/Town <blank>

**State** 

**ZIP/Postal Code** <blank>

**Sender Category** Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that

Consumer

apply)

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

Yes

# **Problem Summary**

**Problem Start Date** 12/12/2018

**Problem End Date** <blank> Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

After using an e-cig, I experienced an extremely short black out that i believe to be a seizure. It lasted for less than 30 seconds and has only happened once. The device was a sourin air with 5% salt nicotine

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

None of the above

Treatment Received (select all that apply)

None

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

1

Select Unit of Time

minute(s)

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

19

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

none

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

zyrtec

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

	Electronic cigarette, electronic nicotine or vaping product(E-cigarette,
Tobacco Product Type	e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal
	vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Glycerin

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating

element?

Unknown

**Full Tobacco Product Name**, including Brand and Sub-Brand (if unknown, please enter "unknown")

Sourin Air

When did the person purchase this product?

12/12/2018

UNIVERSAL PRODUCT **CODE (UPC) from Label** 

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco

<blank>

product?

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is **Every Day** this tobacco product used?

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

4

Select Unit of Measure

Month(s)

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

5

**Select Unit of Measure** 

Second(s)

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

No

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

#### **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

**Tobacco Product Type** Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please Camels

enter "unknown")

Is the tobacco product currently being used?

How is the tobacco product

used?

On average, how often is the tobacco product used?

Inhaled (smoked or vaped)

Rarely

#### **Other Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Sourin Air

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

**Every Day** 

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

## **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

Describe who the problem was reported to

<blank>

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country **United States** Street Address Line 1 Street Address Line 2 <blank> City/Town **State ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer apply) Are you the person who experienced health Yes problems associated with a tobacco product?

# **Problem Summary**

Product Problem Type (select all that apply)

Other

Describe the other product problem

Gave me seizures possibly

In what setting(s) did this problem occur? (select all that apply)

One person using one or more product(s)

Problem Start Date

03/23/2019

**Problem End Date** 

03/24/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Had 2 seizures within 12 hours of each other. Had MRIs, CT scans, EEGs, and few more tests to try to pinpoint the cause but doctors can't seem to find the reason behind the seizures.

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

Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

None

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

<blank>

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)

What is the current status of the health problem?

Not Recovered or Unresolved

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

**Gender** Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

23

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

No health problems or family history of epilepsy prior to vaping tobacco products

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Hydrocodone/Acetaminophen (10/325)

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Uses a tank or tank system, Power (watts) can be changed or adjusted, Voltage can be changed or adjusted, Button activated, Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Candy or Chocolate

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Smok X-Priv Vaporizer

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

<blank>

**Manufacturer Name** 

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

1

Select Unit of Measure	Year(s)
How soon after the tobacco product was last used did the problem occur?	1
Select Unit of Measure	Day(s)
How long has the person been using this particular brand or label?	1
Select Unit of Measure	Year(s)
Did the person continue to use this tobacco product after the problem occurred?	No
Did this same or similar problem happen again after repeat use of the tobacco product?	No
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

# **Attached Files**

None



#### REPORT INFORMATION

## **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-04

FDA ICSR ID

Followup by using your

account



Proxy Report Information (not applicable if this is not a proxy report)

# **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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Confirm Email (b) (6)

First Name (b) (6)

Last Name (b) (6)

Phone (b) (6)

Email (If prefilled, changing this email address will not change your Login email ID)

(b) (6)

Country United States

Street Address Line 1 (b) (6)

City/Town (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that apply)

**State** 

Consumer, Concerned citizen

## **Problem Summary**

Problem Start Date 01/18/2019
Problem End Date 01/19/2019

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

My son experienced two seizures after using a Vape for two years. One was a grand mal seizure.

illioilliation.

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

Life threatening

or more)

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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

**Select Unit of Time** month(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Male

Race (Select all that apply) White

**Ethnicity** <blank>

Birth date of the person who experienced the problem

Age of the person when the

problem occurred

22

**Select Unit of Age** year(s)

Please list any known pre-

existing health problems for None

the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

# What are the main symptoms or health problems?

Term describing the health problem

Clonic seizures

#### **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype <blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please

enter "unknown")

Juul

When did the person purchase this product?

12/23/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco

**United States** 

product?

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

**Manufacturer Name** 

Other

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) <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> **Email Address** <blank>

### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?	Every Day
Are other substances being mixed in with the tobacco product when used?	<black></black>
Did the problem occur with first time use of the tobacco product?	<black></black>
How long has the person been using this type of tobacco product?	<black></black>
Select Unit of Measure	<blank></blank>
How soon after the tobacco product was last used did the problem occur?	<black></black>
Select Unit of Measure	<blank></blank>
How long has the person been using this particular brand or label?	<black></black>
Select Unit of Measure	<blank></blank>
Did the person continue to use this tobacco product after the problem occurred?	No
Did this same or similar problem happen again after repeat use of the tobacco product?	<black></black>
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	Unknown

# **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype <blank>

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

Is the tobacco product currently being used?

No

#### **Other Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype <blank>

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

Is the tobacco product currently being used?

No

### **Additional Information**

# **Attached Files**

None



#### REPORT INFORMATION

## **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-04

FDA ICSR ID

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# **Report Identifying Information**

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Voluntary

Regulatory Status

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	(b) (6)
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	   
Job Title	(b) (6)
Phone	
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	<black></black>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Mother

# **Problem Summary**

Problem Start Date 04/02/2019

Problem End Date <br/>
<

minutes felt light headed, passed out and had a seizure. The seizure was witnessed by friends who called 911. She had on a Garman watch that showed her HR spike from 55 to 165. Upon arrival of the EMS they found her to be responsive but not oriented to place or time. She answered all questions incorrectly as to where she was and what day and year it was. Approximately 20 minutes later she was oriented and last remembered taking the puff off of the Juul and seeing a bright light. She has undergone extensive blood and urine testing for various drugs and alcohol all of which were negative. She was given a CT scan of her head and neck, EKG, ultrasound of her heart all of which were negative. All electrolytes were within normal levels and no notable abnormalities to CBC or CMP. Patient is now scheduled to followup with a neurologist for an MRI and an EEG. She has lost her license to

My daughter took a puff off of a Juul brand e cigarette and within a few

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

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

Life threatening

drive for 3 months.

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

18

Select Unit of Age year(s)

Please list any known preexisting health problems for No health problems the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Lo-estrin (birth control pill) Doxycycline 50mg Twice daily (for acne) zyrtec 10mg daily as needed for allergies

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

electronic nicotine or vaping

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** 

vaporizer

Select all that apply to the electronic cigarette, Disposable (non-refillable) product product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Glycerin, Propylene Glycol, Other

Describe other e-liquid ingredients

natural oils, extracts, glycerol, benzoic acid

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul Mango 5% nicotine pod

When did the person purchase this product?

04/01/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of

manufacture of the tobacco

**United States** 

product?

Where is the tobacco product now?

Product was discarded

How was this product acquired?

In a Store

Do you know where the product was purchased?

No

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location 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> **Email Address** <blank>

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?	Rarely
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	Yes
How long has the person been using this type of tobacco product?	<black></black>
Select Unit of Measure	<black></black>
How soon after the tobacco product was last used did the problem occur?	3
Select Unit of Measure	Minute(s)
How long has the person been using this particular brand or label?	<black></black>
Select Unit of Measure	<black></black>
Did the person continue to use this tobacco product after the problem occurred?	No
Did this same or similar problem happen again after repeat use of the tobacco product?	N/A - Person did not restart use
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. This was a high school student who did this in the school parking lot and almost immediately fell unconscious and had a seizure. Thankfully she was parked and not driving when this happened. She was nicotine Naive but a seizure is an extreme reaction in an otherwise healthy athletic child. These products are unsafe and should be removed from the market.

## **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country <blank> Street Address Line 1 Street Address Line 2 City/Town State **ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer, Concerned citizen apply) Are you the person who experienced health Yes problems associated with a

# **Problem Summary**

tobacco product?

Problem Start Date 12/01/2018
Problem End Date 12/19/2018

**Please describe the health** I was using a Suorin Air. A nicotine device just as I normally have for **problem or product problem.** about a year and then I randomly passed out and had a siezure. This

The Attachments page will accept uploads of any records, pictures, or other information.

happened 3 times during the month of December. They lasted for about a minute each

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

Life threatening

Treatment Received (select

None

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

1

......

all that apply)

Select Unit of Time minute(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each

affected person, if possible.)

User(s)

How many users were

affected? <br/>
<br/>

**Gender** Male

Race (Select all that apply) White

Ethnicity <br/>
<b

Birth date of the person who experienced the problem



Age of the person when the problem occurred

19

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

General anxiety disorder

# **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Lexapro

# What are the main symptoms or health problems?

Term describing the health problem

Partial seizures, simple

#### **Tobacco Products**

Tobacco Product Type	Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)
Tobacco Product Subtype	E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer
Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)	Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

for your electronic cigarette, Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Glycerin, Propylene Glycol

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

I was using the Suorin Air to vaporize Salty Man Kool Peach e-liquid

When did the person purchase this product?

08/08/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for

example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco

China

product?

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

Online Order

Do you know where the product was purchased?

No

**Manufacturer Name** 

Other

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) Suorin

Country **United States** 

**Phone** <blank>

Street Address Line 1 <blank>

**Street Address Line 2** <blank>

City/Town <blank>

**State** <blank>

**ZIP/Postal Code** <blank>

**Web Address** <blank>

**Email Address** <blank>

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is **Every Day** this tobacco product used?

Are other substances being mixed in with the tobacco No

product when used?

Did the problem occur with first time use of the tobacco No

product?

How long has the person been using this type of tobacco product?

1

**Select Unit of Measure** Year(s)

How soon after the tobacco	
product was last used did	30
the problem occur?	

Select Unit of Measure Second(s)

How long has the person been using this particular brand or label?

3

Select Unit of Measure Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

## **Other Products Used**

## **Other Tobacco Products**

#### **Additional Information**

# **Attached Files**

None



#### REPORT INFORMATION

## **Report Profile**

Report Version FPSR.FDA.CTP.V.V3

**Report Category** Tobacco Product Report V3

**Submitted** 2019-04-04

FDA ICSR ID

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# **Report Identifying Information**

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Voluntary

**Type of Submission** 

**Regulatory Status** 

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside <br/>
SRP)?

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

**Organization Name** <blank> **Confirm Email First Name** (b) (6) **Last Name** Did you report the problem No to the manufacturer? Job Title <blank> **Phone** Email (If prefilled, changing this email address will not (b) (6) change your Login email ID) Country United States Minor Outlying Islands Street Address Line 1 Street Address Line 2 <blank> City/Town State/Province **ZIP/Postal Code Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer

Yes

# **Problem Summary**

problems associated with a

apply)

Are you the person who experienced health

tobacco product?

Problem Start Date 02/01/2017

Problem End Date <br/>
<

Please describe the health I STARTED USING E-CIG PRODUCTS ABOUT 5 YEARS AGO. problem or product problem. ABOUT 2 YEARS AGO I STARTED HAVING ISSUES WITH HAVING

The Attachments page will accept uploads of any records, pictures, or other information.

MINI BLACK OUT AND HEADACHES. I DID NOT KNOW WHAT WAS CAUSING THEM AND DID NOT HAPPEN ALL OF THE TIME. FOR THE PAST YEAR THE HEADACHES AND BLACK OUTS CAME MORE AND WERE MORE INTENSE TO THE POINT THAT I HAD TO SEE A DOCTOR. IT WAS DETERMINED THAT I WAS HAVING MINI SIEZURES AND WAS TAKING OFF WORK FOR A MONTH AND NO DRIVING TO GET IT UNDER CONTROL. I AM GOING ON MY 3RD MONTH OF TAKING DEPAKOTE 500 MG A DAY. I AM STILL HAVE SOME ISSUES BUT HOPING THAT WITH CONTINUE TREATMENT IT WILL WORK. I HAVE BEEN TOLD THAT I WILL HAVE TO BE ON THESE MEDS FOR THE REST OF MY LIFE.

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

Lasting disability or other permanent health problem, Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

I AM CURRENTLY RECEIVING TREATMENT WITH MEDS AND BLOOD WORK MONTHLY TO CHECK MY DEPAKOTE LEVELS. I HAVE HAD AN EEG AND CATSCAN

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Female

**Pregnant** No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

**Select Unit of Age** 

year(s)

Please list any known preexisting health problems for <blank> the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

DEPAKOTE 500 MG A DAY

## What are the main symptoms or health problems?

Term describing the health problem

Frequent headaches

## What are the main symptoms or health problems?

Term describing the health problem

Partial seizures, simple

#### **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Mixed in a shop or on-line per request or "to order"

Describe the e-liquid mix <blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Coloring Agents, Flavor(s), Glycerin

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Tobacco, Fruit, Candy or Chocolate, Combination/mixture of flavors

Was the e-liquid dripped on to the atomizer or heating element?

Yes

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

**UNKNOWN** 

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

Where is the tobacco product now?

<blank>

How was this product

acquired?

<blank>

Do you know where the product was purchased?

<blank>

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

# **Tobacco Product Manufacturer Information**

# **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?

Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	<blank></blank>
Select Unit of Measure	<blank></blank>
How soon after the tobacco product was last used did the problem occur?	<blank></blank>
Select Unit of Measure	<blank></blank>
How long has the person been using this particular brand or label?	<blank></blank>
Select Unit of Measure	<blank></blank>
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

# **Other Products Used**

# **Other Tobacco Products**

# **Additional Information**

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-04

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Last Name <black>

Did you report the problem to the manufacturer?

<blank>

Job Title <br/>
Phone <br/>
<b

Email (If prefilled, changing this email address will not change your Login email ID)

<blank>

State <br/> <br/>

ZIP/Postal Code <br/> <b

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that Concerned citizen

apply)

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

<blank>

# **Problem Summary**

Problem Start Date 02/02/2019

Problem End Date <br/>
<

Please describe the health problem or product problem.

Seizures related to vaping

The Attachments page will accept uploads of any records, pictures, or other information.

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

Lasting disability or other permanent health problem

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

MRI, CT Scan, blood work, neurology visits, prescribed seizure medications

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

<blank>

**Select Unit of Time** 

<blank>

What is the current status of the health problem?

<blank>

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

Nonuser(s)

How many nonusers were

1

affected? Gender

Male

Race (Select all that apply)

White

**Ethnicity** 

Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

26

Select Unit of Age

year(s)

Please list any known preexisting health problems for ADHD the affected person

**Medications and Supplements** 

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Seizures

# **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** <blank>

Select all that apply to the electronic cigarette, electronic nicotine or vaping <blank> product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the <blank> following? (select all that apply) Was the e-liquid dripped on to the atomizer or heating <blank> element? Full Tobacco Product Name, including Brand and Sub-Unknown Brand (if unknown, please enter "unknown") When did the person <blank> purchase this product? **UNIVERSAL PRODUCT** <blank> CODE (UPC) from Label Does the involved product device or package bear the Don't Know "UL" symbol? Any other identifying tobacco product codes (for example, SKU, item/catalog <blank> number, manufacturing date/ batch code) What is the country of manufacture of the tobacco <blank> product? Where is the tobacco <blank> product now? How was this product <blank> acquired? Do you know where the <blank> product was purchased?

**Manufacturer Name** 

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is **Every Day** this tobacco product used?

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

<black>

**Select Unit of Measure** 

<blank>

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

<blank>

**Select Unit of Measure** 

<blank>

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

**Tobacco Product Type** 

Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

# **Attached Files**

None



# REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-05

FDA ICSR ID (b) (6)

Report Key for Followup

(b) (6)

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Sender Category Consumer/Concerned Citizen (FdaTPR)

## **Problem Summary**

Problem Start Date 12/25/2018

Problem End Date <br/>
<

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

I think my son had nicotine poisoning from the juul. He vomits and then has a seizure. My son is not epileptic, but now they think he could be! I am not convinced.

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

Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Anti seizure meds

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)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a

User(s)

separate report for each affected person, if possible.)

How many users were

affected?

<blank>

Gender Male

Race (Select all that apply) White

**Ethnicity** <blank>

Birth date of the person who experienced the problem



Age of the person when the

problem occurred

18

Select Unit of Age year(s)

Please list any known preexisting health problems for <blank>

the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Seizures

#### **Tobacco Products**

batch code)

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice) E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** vaporizer Select all that apply to the electronic cigarette, Rechargeable product, Uses prefilled cartridge, cart, cartomizers or electronic nicotine or vaping carto., Puff/flow activated product (including electronic waterpipe) Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, Purchased for use in a capsule, tank or refillable cartridge electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the Nicotine, Flavor(s) following? (select all that apply) What type(s) of flavor(s) does the e-liquid contain? Mint (such as wintergreen or spearmint) (select all that apply) Was the e-liquid dripped on to the atomizer or heating No element? Full Tobacco Product Name, including Brand and Sub-Juul Brand (if unknown, please enter "unknown") When did the person 12/12/2018 purchase this product? **UNIVERSAL PRODUCT** <blank> CODE (UPC) from Label Does the involved product device or package bear the Don't Know "UL" symbol? Any other identifying tobacco product codes (for example, SKU, item/catalog <blank> number, manufacturing date/

What is the country of manufacture of the tobacco United States

product?

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

## **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

**Every Day** 

Are other substances being mixed in with the tobacco product when used?	Unknown
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	<blank></blank>
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the problem occur?	<blank></blank>
Select Unit of Measure	Minute(s)
How long has the person been using this particular brand or label?	<blank></blank>
Select Unit of Measure	Month(s)
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

# **Tobacco Product Parts**

# **Other Products Used**

# **Other Tobacco Products**

# **Additional Information**

# **Attached Files**

None



### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-05

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	(b) (6)
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	(b) (6)
Phone	
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	(b) (6)
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	
Sender Category	Healthcare Professional (FdaTPR)
Healthcare Professional type	Physician
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Patient

# **Problem Summary**

Problem Start Date 01/25/2019

Problem End Date 01/25/2019

Please describe the health problem or product problem. The Attachments page

will accept uploads of any records, pictures, or other information. Generalized tonic-clinic seizure

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

Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

MRI - congenital area of cortical dysmyelinosis (unrelated); ambulatory EEG-normal

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

Select Unit of Time day(s)

What is the current status of the health problem?

Recovered or Resolved

### **Affected Person**

Affected Person Identifier Code



Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Female

Pregnant No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

17

Select Unit of Age

year(s)

Please list any known preexisting health problems for None the affected person

### **Medications and Supplements**

Please list the prescription medications, over-thecounter medications. vitamins, and/or supplements taken around the time of the health problem.

Blivosi (birth control pill), Advil

### What are the main symptoms or health problems?

Term describing the health problem

Tonic-clonic seizures

### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the e-Purchased in a non-refillable disposable cartridge liquid, e-juice or vape juice

for your electronic cigarette, electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Suorin Drop/Naked 100e Liquid/Hawai'ian Pog

When did the person purchase this product?

//2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Unknown

How was this product acquired?

In a Store

Do you know where the product was purchased?

No

**Manufacturer Name** 

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

### **Tobacco Product Purchase Location**

### **Tobacco Product Manufacturer Information**

### **Tobacco Product Use Details**

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	<black></black>
Are other substances being mixed in with the tobacco product when used?	<blank></blank>
Did the problem occur with first time use of the tobacco product?	Yes
How long has the person been using this type of tobacco product?	<black></black>
Select Unit of Measure	<black></black>
How soon after the tobacco	

<blank>

product was last used did <blank>

the problem occur?

Select Unit of Measure

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

### **Other Tobacco Products**

### **Additional Information**

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

Only the obvious- These things should be removed from the market

problem. Attachments may be added on the next page.

# **Attached Files**

None

CTU No.: FDA-CDER-CTU-2019-60 (5) | Department: CTP | RCT No.: RCT-60 (6) | CTU Triage Date: 05-04-2019 | Total Pages:

All dates displayed in the report are in EST(GMT-05:00) time zone

Contact

Basic Details		No. of the Control of	3.5
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	1	*
Override Auto Calculation Rule	No		
FDA Received Date	04-Apr-2019	CTU Received Date	04-Apr-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		***************************************
User/Group			
Forward to Department	CDER (CDER-C	OSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem			
	ind of problem was it? all that apply)	Used a product incorrectly with the o	effect (including new or worsening symptor which could have or led to a problem quality of the product g from one product maker to another maker	
Date the	e problem occurred	12-Mar-2019		
Serious	5	Yes		
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent pe Disability or health problem Birth defect Life-threatening Death Other serious/important med	rmanent harm	
The second secon	erious/important medical t(Please Describe Below)	My daughter has seizure		

# 4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I am a juul user. I have used this product since August 2018. On 3/12/2019, my daughter had seizure first time, and she stay in the hospital for several days, she was diagnosed with seizure disorder. The doctor could not specify what is the reason for causing the seizure, neither me and me wife. Today, we saw news on social media which indicated that juul might cause seizure, so I am wondering that my daughter was harmed by me using juul e-cigarette. I want to know any other family face the same problem just like me? My daughter is 14 months, and I don't want any other family could be harmed by such product.

Relevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	

Receipt No: RCT-(b) (6) FDA 3500B Form

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 (6) | Department: CTP | RCT No.: RCT-(9) (6) | CTU Triage Date: 05-04-2019 | Total Pages: 6

	More Information Available?						
Ad	lditional Comments						
Se	ection B - Product Availability						
	Do you still have the product in case we need to evaluate it?	Yes					
	Do you have a picture of the product? (check yes if you are including a picture)	Yes					
Se	ection C - About the Products					1 of 1	
	Suspect	Yes					П
П	Primary?	Yes					
	Туре	Drug/Biologic					
	This report is about	Drug					
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	JUUL					
	Name of the company that makes (or compounds) the product	JUUL					
	Product Type(check all that apply)	Over-the-Counter Compounded by a Generic Biosimilar		Outsourcing Facility			
	Strength		lf (	Other			
	NDC number						
	Did the problem stop after the person reduced the dose or stopped taking or using the product?						
	Did the problem return if the person started taking or using the product again?						
Dr	ug Therapy					1 of 1	
1	Expiration date						11
	Lot number						
	Dosage Form						
	Quantity		lf (	Other			
	Frequency		lf (	Other			41
	How was it taken or used		lf (	Other	-+ -+		
	Date the person first started taking or using the product						
	Date the person stopped taking						

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Receipt No: RCT-(b) (6) FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019-(5) (6) | Department: CTP | RCT No.: RCT-(6) (6) | CTU Triage Date: 05-04-2019 | Total Pages:

Give best estimate of duration		r la
Is therapy still on-going?		
The state of the s	product? (such as what condition was it supposed to treat) 1 of 1	Ė
		ij.
Returned to Manufacturer On		
Section D - About the Medical D	)evice	
Name of medical device	The state of the s	
Name of the company that		Ħ
makes the medical device		Ш
Other identifying information (1) locate them)	he model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
		1
		Ш
Model Number		
Catalog Number		
Lot Number		
Serial Number		Ĭ.
UDDI Number		
Expiration date		
Was someone operating the medical device when the proble occurred?	m	
For implanted medical devices	ONLY (such as pacemakers, breast implants, etc.)	
Date the implant was put in	Date the implant was taken out (If relevant)	
Section E - About the Person W	/ho Had the Problem	
Person's Initials	(0) (0)	
Gender	Female	
Age (specify unit of time for age		
Date of Birth	(b) (6)	
Weight		
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaskan Native	
	Native Hawaiian or Other Pacific Islander	
	Asian	
	White	
	Black or African American	+

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

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	Seizure Disorder		
ΙPΙ	ease list all allergies (such	as to drugs, foods, pollen or others)	
Li	st any other important infor	mation about the person (such as smoking, pregnancy, alcohol use, etc.)	
		er had been exposed two second-hand smoking.	11111
	st all current prescription m	edications and medical devices being used.	
TIP	st all over-the-counter med	ications and any vitamins, minerals, supplements, and herbal remedies being used	
Se	ection F - About the Person		
	Primary?	(b) (c)	
	Reporter is Patient?		1 17
	Title		
	Last name	(b) (6)	
	Middle Name		1 1
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(5) (5)	
	Country	USA	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	T)E
	Fax		
	Reporter Organization		
		4	

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Reporter Speciality

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (0) | Department: CTP | RCT No.; RCT-(0) (6) | CTU Triage Date: 05-04-2019 | Total Pages; 6

Today's date	04-Apr-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM 04-Apr-2019 23:45:29 Page 5 of 5 Generated on:





### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-05

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

(b) (6)

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

(max length: 50 characters)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

### **Contact Information - Sender**

**Organization Name** <blank> **Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? **Job Title** <blank> **Phone** <blank> Email (If prefilled, changing this email address will not (b) (6) change your Login email ID)

**Country** United States

Street Address Line 1 <blank>
Street Address Line 2 <blank>
City/Town <blank>
State <blank>
ZIP/Postal Code <blank>

Sender Category Healthcare Professional (FdaTPR)

Healthcare Professional type Physician

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

No

Describe your relationship to the person who experienced the health problem

Health provider

### **Problem Summary**

Problem Start Date 01/01/2019

Problem End Date 01/01/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Patient had a generalized seizure lasting approximately 3 minutes immediately after using a nicotine vape device. He had used device in past, but inhaled several times in the minutes leading up to seizure. Thorough evaluation was performed for first time seizure including brain imaging with MRI and EEG. No alternative cause was identified.

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

Other serious medical event

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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

3

Select Unit of Time

minute(s)

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Affected Person Identifier Code

<blank>

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

1

affected? Gender

Male

Race (Select all that apply)

White

**Ethnicity** 

Not Hispanic or Latino

Birth date of the person who experienced the problem

b) (6)

Age of the person when the problem occurred

18

**Select Unit of Age** 

year(s)

Please list any known preexisting health problems for none the affected person

### **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

### What are the main symptoms or health problems?

Term describing the health problem

Tonic-clonic seizures

#### **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype <blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the

<blank>

"UL" symbol?

Any other identifying tobacco product codes (for example, SKU, item/catalog <br/>number, manufacturing date/ batch code) <br/>

What is the country of manufacture of the tobacco

<blank>

product?

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

<blank>

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

**Tobacco Product Purchase Location** 

**Tobacco Product Manufacturer Information** 

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used? On average, how often is <blank> this tobacco product used? Are other substances being mixed in with the tobacco <blank> product when used? Did the problem occur with first time use of the tobacco No product? How long has the person been using this type of <blank> tobacco product? **Select Unit of Measure** <blank> How soon after the tobacco product was last used did <blank> the problem occur? **Select Unit of Measure** <blank> How long has the person been using this particular <blank> brand or label? **Select Unit of Measure** <blank> Did the person continue to use this tobacco product Unknown after the problem occurred? Did this same or similar problem happen again after No repeat use of the tobacco product? Did the person change the product in any way before using it (for example, <blank>

#### **Tobacco Product Parts**

removing a filter from a

cigarette)?

### **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

### **Other Tobacco Products**

### **Additional Information**

Please describe anything
else you think the FDA
should know about this
problem. Attachments may
be added on the next page.

### **Attached Files**

None



### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-05

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

### **Contact Information - Sender**

**Organization Name** <blank> <blank> **Confirm Email First Name Last Name** (b) (6) Did you report the problem No to the manufacturer? Job Title <blank> **Phone** <blank> Email (If prefilled, changing this email address will not <blank> change your Login email ID) Country **United States** Street Address Line 1 <blank> Street Address Line 2 <blank> City/Town <blank> **State** <blank> **ZIP/Postal Code** <blank> **Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Concerned citizen apply) Are you the person who experienced health No

Mother

### **Problem Summary**

problems associated with a

Describe your relationship

tobacco product?

to the person who

problem

experienced the health

 Problem Start Date
 07/19/2018

 Problem End Date
 07/19/2018

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Seizures after using a "Jewel" E Cigarette Also he got a bacterial infection and had to have it surgically cleaned out. It was a staff infection and he could have lost his arm if not taken care of.

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

Life threatening, Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

For the seizure he had an MRI and numerous other neurological tests. For the bacterial infection, he had surgery.

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

Select Unit of Time week(s)

What is the current status of the health problem?

Recovered or Resolved

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

**Gender** Male

Race (Select all that apply) White

**Ethnicity** Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

14

**Select Unit of Age** 

year(s)

Please list any known preexisting health problems for NA the affected person

### **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

### What are the main symptoms or health problems?

Term describing the health problem

Seizure

### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** <blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown

When did the person purchase this product?

UNIVERSAL PRODUCT CODE (UPC) from Label

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog <br/>number, manufacturing date/ batch code) <br/>

How was this product acquired? <br/>

Do you know where the product was purchased? <black</pre>

Manufacturer Name <br/> <br/>

**Tobacco Product Packaging and Portions** 

**Manufacturer Investigation Information** 

**Tobacco Product Purchase Location** 

### **Tobacco Product Manufacturer Information**

### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Some Days

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco product?

No

How long has the person been using this type of tobacco product?

1

**Select Unit of Measure** 

Year(s)

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

1

**Select Unit of Measure** 

Week(s)

How long has the person been using this particular brand or label?

<blank>

**Select Unit of Measure** 

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

No

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

Unknown

**Tobacco Product Parts** 

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

**Attached Files** 

None

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 to) (6) | Department: CTP | RCT No.; RCT-10) (6) | CTU Triage Date: 05-04-2019 | Total Pages; 5

All dates displayed in the report are in EST(GMT-05:00) time zone

ompany Unit		CDER-CTU	Originating Account	FAERS
ource Medium	¢	MWO (Drug)	Source Form Type	E2B XML 3500B
riority		Routine	4	0
verride Auto Ca	alculation Rule	No		
DA Received D	ate	04-Apr-2019	CTU Received Date	05-Apr-2019
TU Triage Date			CTU Data Entry Date	
eport Type		Spontaneous	Report Classification	Drug
ssign To		User		
ser/Group				
orward to Depa	rtment	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
ase Priority		Direct		
ntact	Lavin	No. in con-	0.000	515
ase Firs	st Name	Last Name	Email Address	Phone
(b)	(6)	(b) (6)	(b) (6)	(b) (6)
ction A - Abc	out the Problem			
What kind of	problem was it?			
(Check all tha	00244	Used a product income Noticed a problem with	ed side effect (including new or worsening sympto ectly which could have or led to a problem h the quality of the product witching from one product maker to another make	
(Check all that	at apply)	Used a product incorred Noticed a problem with Had problems after sw	ectly which could have or led to a problem h the quality of the product	
(Check all that Date the prob	at apply)	Used a product income Noticed a problem with	ectly which could have or led to a problem h the quality of the product	
(Check all that Date the prob	at apply)  blem occurred e following happen?	Used a product income Noticed a problem with Had problems after sw 10-Feb-2017  Yes  Hospitalization - admit Required help to prevent Disability or health problems after sw 10-Feb-2017	ectly which could have or led to a problem th the quality of the product witching from one product maker to another make tted or stayed longer ent permanent harm oblem	
Date the prob Serious Did any of the (Check all that	at apply)  elem occurred  e following happen? at apply)	Used a product incorred Noticed a problem with Had problems after sw 10-Feb-2017  Yes  Hospitalization - admit Required help to preven Disability or health problems Birth defect Life-threatening Death Other serious/important	ectly which could have or led to a problem th the quality of the product witching from one product maker to another make tted or stayed longer ent permanent harm oblem  Int medical incident(Please Describe Below)	or
Date the prob Serious Did any of the (Check all that	at apply)  elem occurred  e following happen? at apply)	Used a product income Noticed a problem with Had problems after sw 10-Feb-2017  Yes  Hospitalization - admit Required help to preven Disability or health problems after sw Disability or health problems. Death Other serious/importaty it happened (Included)	ectly which could have or led to a problem th the quality of the product witching from one product maker to another make tted or stayed longer ent permanent harm oblem	or
Date the prob Serious Did any of the (Check all that	at apply)  blem occurred  e following happen?  at apply)  nappened and how	Used a product income Noticed a problem with Had problems after sw 10-Feb-2017  Yes  Hospitalization - admit Required help to preven Disability or health problems after sw Disability or health problems. Death Other serious/importaty it happened (Included)	ectly which could have or led to a problem th the quality of the product witching from one product maker to another make  tted or stayed longer ent permanent harm oblem  nt medical incident(Please Describe Below)  ude as many details as possible F	or

evant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	
More Information Available?		

CTU No.: FDA-CDER-CTU-2019-01 (5) | Department: CTP | RCT No.: RCT-0) (5) | CTU Triage Date: 05-04-2019 | Total Pages: 5

ection B - Product Availability				
	Take-			
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
ection C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Drug			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	JULE			
Name of the company that makes (or compounds) the product				
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmac Generic Biosimilar	y or an Outsourcing Facility		
Strength		If Other		
NDC number			312	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
rug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form		2		
Quantity		If Other		
Frequency		If Other		
How was it taken or used	Respiratory (inhalation)	If Other		
Date the person first started taking or using the product	11-Oct-2016		*	
Date the person stopped taking or using the product	10-Mar-2018			
Give best estimate of duration				

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Receipt No: RCT-(b) (6) FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-00 (6) | Department: CTP | RCT No.: RCT-(0) (6) | CTU Triage Date: 05-04-2019 | Total Pages:

	Is therapy still on-going?		
VVI	ny was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Otl loc	her identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
_	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o Had the Problem	
	Person's Initials	STEP	
	Gender	Male	
	Age (specify unit of time for age)		
	Date of Birth	(b) (6)	
	Weight	90 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

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Receipt No: RCT-(b) (6) FDA 3500B Form CTU No.: FDA-CDER-CTU-2019-(b) (6) | Department: CTP | RCT No.: RCT-(b) (6) | CTU Triage Date: 05-04-2019 | Total Pages: 5

Ple	ease list all allergies (such	as to drugs, foods, pollen or others)	
Lis	t any other important infor	mation about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	t all current prescription m	edications and medical devices being used.	
	Briviact		
Lis	st all over-the-counter med	ications and any vitamins, minerals, supplements, and herbal remedies being use	d.
Se	ection F - About the Person	Filling Out This Form 1 of	1
Se	ection F - About the Person Primary?	Filling Out This Form 1 of	
Se	ection F - About the Person Primary? Reporter is Patient?		1
Se	Primary?		1
Se	Primary? Reporter is Patient?	Yes	1
Se	Primary? Reporter is Patient? Title		1
Se	Primary? Reporter is Patient? Title Last name	Yes	
Se	Primary? Reporter is Patient? Title Last name Middle Name	Yes	1
Se	Primary? Reporter is Patient? Title Last name Middle Name First name	Yes (b) (6)	1
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	Yes (b) (6) (b) (6)	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City	Yes (b) (6) (b) (6)	1
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	Yes (b) (6) (b) (6) (b) (6)	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	Yes  (b) (6)  (b) (6)  (b) (6)	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code	Yes (b) (6) (b) (6) (b) (6) (b) (6)	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number	Yes  (b) (6)  (b) (6)  (b) (6)  (b) (6)  (b) (6)	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address	Yes  (b) (6)  (b) (6)  (b) (6)  (b) (6)  (b) (6)	1
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address Fax	Yes  (b) (6)  (b) (6)  (b) (6)  (b) (6)  (b) (6)	

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Receipt No: RCT-(b) (6) FDA 3500B Form

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Today's date	04-Apr-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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Receipt No: RCT-(b) (6) FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-00 (b) | Department: CTP | RCT No.: RCT-(D) (6) | CTU Triage Date: 04-04-2019 | Total Pages:

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		The second second	A Second
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	04-Apr-2019	CTU Received Date	04-Apr-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		16
User/Group			
Forward to Department	CDER (CDER-C	OSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact	A STATE OF THE STA		45 To 10 To 10 To 10	1966
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(5) (U)	(b) (6)	(b) (6)
section A	- About the Problem			
	nd of problem was it? all that apply)	Used a product incorrectly w	effect (including new or worsening sympton hich could have or led to a problem quality of the product g from one product maker to another maker	
Date the	e problem occurred	14-Sep-2018		
Serious		Yes		
	of the following happen? all that apply)	Hospitalization - admitted or		

## 4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Other serious/important medical incident(Please Describe Below)

Disability or health problem

Birth defect
Life-threatening

Seizure

Other serious/important medical incident(Please Describe Below)

My son, 17 years old, took a "hit" off of a friends vaping device, at school, in a locker room. He immediately had a seizure and was taken by ambulance to the hospital. Two months later, in spite of all of our warnings (and threats) from both of his parents as to how dangerous what happened to him was, he took again smoked his friends vaping device, this time in a stairwell at his high school, in the morning, between classes. He again had a seizure and this time fell down a flight of stairs, and was transported to the hospital by ambulance. Again in this incident, he stated that he "took a couple if hits." This has not happened again. I believe he is scared of the reaction he has with this product. But I wanted to report this to the FDA because of the article I read about stating that there had been 35 reports of seizures related to vaping. I am curious as to whether this is due to nicotine poisoning, or what the cause it. My son is otherwise very healthy, strong, and athletic. I would like to report his case because I believe it could have been fatal, if not the seizure, certainly a passed out unconscious fall down a flight of stairs. I believe that these vaping products are clearly and unknown product, and they have the potential to cause major harm. Please share any information, or if you need any from me, please let me know.

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Receipt No: RCT-(b) (6)

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Re	elevant Test/Laboratory Data		-		1 of 1	
	Test Name		Test Date			
	Test Result		Test Unit			
	Low Test Range	_	High Test Range			
	More Information Available?					
Ac	Iditional Comments					
, ,,	antional comments					
Se	ection B - Product Availability					
	Do you still have the product in case we need to evaluate it?	No				
	Do you have a picture of the product? (check yes if you are including a picture)	No				
Se	ection C - About the Products				1 of 1	
	Suspect	Yes				
	Primary?	Yes			73 Lu	
	Туре	Drug/Biologic				
	This report is about	Cosmetic, Dietary Sup	plement or Food/Medicinal	Food	PT.	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Juele				
	Name of the company that makes (or compounds) the product	Vap				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pha Generic Biosimilar	rmacy or an Outsourcing Facility			
	Strength		If Other			H
	NDC number		-			
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes				
	Did the problem return if the person started taking or using the product again?	Yes				ŀ
Dr	ug Therapy				1 of 1	
	Expiration date					
	Lot number					
	Dosage Form		1			14
1	Quantity		If Other			15

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Weight

Ethnicity (Choose only one)

Race (Check all that apply)

If Other Frequency How was it taken or used If Other Date the person first started 14-Sep-2018 taking or using the product Date the person stopped taking 22-Oct-2018 or using the product Give best estimate of duration Is therapy still on-going? |Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number **UDDI Number** Expiration date Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Male Gender 17 Year(s) Age (specify unit of time for age) Date of Birth

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63 kg

Not Hispanic/Latino

American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Receipt No: RCT-(b) (6) FDA 3500B Form CTU No.: FDA-CDER-CTU-2019-(b) (6) | Department: CTP | RCT No.: RCT-(b) (6) | CTU Triage Date: 04-04-2019 | Total Pages: 5

		Asian White Black or Africa	ın American		
Li	st known medical conditior	ns (Such as diabete	es, high blood pressure, cancer, hea	art disease, or others)	
	none				
P	ease list all allergies (such	as to drugs, foods	s, pollen or others)	1	
	none		XI.		_
	7				
Li	st any other important info	rmation about the p	person (such as smoking, pregnanc	y, alcohol use, etc.)	
	none				
	1				
Li	st all current prescription n	nedications and me	edical devices being used.		
	none				ī
4					
Li	st all over-the-counter med	lications and any v	itamins, minerals, supplements, and	l herbal remedies being used.	
	none				ī
	1				
9	ection F - About the Persor	n Filling Out This F	orm	1 of 1	
	Primary?	Yes	OIII.	1011	
	Reporter is Patient?				
	Title				ī
	Last name	(b) (d)			ī
	Middle Name				Ī
	First name	(b) (6)			7
	Number/Street	(b) (6)	7		ī
	City	(b) (6)	* i		ī
	State/Province	(0)(5)			ī
	Country	USA			ī
	ZIP or Postal code	(b) (6)			ī
	Telephone number	(b) (6)			1
	Email address	(b) (6)			ī

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Fax		1
Reporter Organization		13
Department		
Reporter Speciality	- T-	
Today's date	04-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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FDA 3500B Form
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dole Dete	ails			
Company l	Jnit	CDER-CTU	Originating Account	FAERS
Source Medium		MWO (Drug)	Source Form Type	E2B XML 3500B
Priority Override Auto Calculation Rule FDA Received Date CTU Triage Date		Routine		
		No		
		04-Apr-2019	CTU Received Date	04-Apr-2019
			CTU Data Entry Date	
Report Typ	e	Spontaneous	Report Classification	Drug
Assign To		User	1	
User/Group	)			
orward to	Department	OCDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priori	ty	Direct	52 1108 010@ida.iiii0.gov) (228)	
Reporter				
ection A	X - About the Problem nd of problem was it?	X  Were hurt or had a bad	side effect (includina new or worsenina sympto	oms)
What ki (Check	- About the Problem nd of problem was it? all that apply)	Were hurt or had a bad Used a product incorrec Noticed a problem with the	side effect (including new or worsening sympto tty which could have or led to a problem the quality of the product ching from one product maker to another make	
What ki (Check	- About the Problem nd of problem was it? all that apply)	Were hurt or had a bad Were hurt or had a bad Used a product incorrec Noticed a problem with Had problems after swit	tly which could have or led to a problem	
What ki (Check Date the Serious	- About the Problem nd of problem was it? all that apply)	Were hurt or had a bad Used a product incorrect Noticed a problem with the Had problems after switt 15-Mar-2019 Yes Hospitalization - admittet Required help to prevent Disability or health problems Birth defect Life-threatening Death	tly which could have or led to a problem the quality of the product ching from one product maker to another make ed or stayed longer tt permanent harm	

elevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	
More Information Available?		

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019-01 (6) | Department: CTP | RCT No.; RCT-19) (6) | CTU Triage Date: 04-04-2019 | Total Pages;
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Additional Comments				
Section B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			ill
Do you have a picture of the product? (check yes if you are including a picture)	No			
Section C - About the Products			1 of	1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Drug			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	JUUL e-cigarette			
Name of the company that makes (or compounds) the product	JUUL			
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmac Generic Biosimilar	y or an Outsourcing Facility		
Strength		If Other		
NDC number			1	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Yes			
Drug Therapy			1 of	1
Expiration date				
Lot number				
Dosage Form			7	
Quantity		If Other		
Frequency		If Other		
How was it taken or used	Respiratory (inhalation)	If Other	- 4	
Date the person first started taking or using the product			<u> </u>	
Date the person stopped taking or using the product				
Give best estimate of duration	2 Year			

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Receipt No: RCT-(b) (6) FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019-(5) (6) Department: CTP | RCT No.: RCT-(5) (6) | CTU Triage Date: 04-04-2019 | Total Pages;

Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 to help quit cigarette smoking Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can Model Number Catalog Number Lot Number Serial Number **UDDI Number** Expiration date Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Unspecified Gender Male 21 Year(s) Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American

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

ase list all allergies (suc	h as to drugs, foods, pollen or others)	
any other important inf	ormation about the person (such as smoking, pregnancy, alc	ohol use, etc.)
alcohol use		
all current prescription	medications and medical devices being used.	
gabapentin for migraines,	anti-anxiety medication	
all over-the-counter me	edications and any vitamins, minerals, supplements, and hert	bal remedies being used.
all over-the-counter me	edications and any vitamins, minerals, supplements, and her	bal remedies being used.
all over-the-counter me	edications and any vitamins, minerals, supplements, and hert	bal remedies being used.
all over-the-counter me	edications and any vitamins, minerals, supplements, and her	bal remedies being used.
all over-the-counter me	edications and any vitamins, minerals, supplements, and her	bal remedies being used.
ction F - About the Pers	on Filling Out This Form	bal remedies being used.
ction F - About the Pers Primary?		
ction F - About the Pers Primary? Reporter is Patient?	on Filling Out This Form	
ction F - About the Pers Primary? Reporter is Patient? Title	on Filling Out This Form Yes	
ction F - About the Pers Primary? Reporter is Patient? Title Last name	on Filling Out This Form	
ction F - About the Pers Primary? Reporter is Patient? Title Last name Middle Name	on Filling Out This Form  Yes  X	
ction F - About the Pers Primary? Reporter is Patient? Title Last name Middle Name First name	on Filling Out This Form Yes	
ction F - About the Pers Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	on Filling Out This Form  Yes  X	
ction F - About the Perse Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	on Filling Out This Form  Yes  X	
ction F - About the Pers Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	on Filling Out This Form  Yes  X	
ction F - About the Perse Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	on Filling Out This Form  Yes  X	
ction F - About the Pers Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	on Filling Out This Form  Yes  X	

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Reporter Organization

Reporter Speciality

Department

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Today's date	04-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 to (6) | Department: CTP | RCT No.: RCT-(9) (6) | CTU Triage Date: 04-04-2019 | Total Pages: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

asic Details			
company Unit	CDER-CTU	Originating Account	FAERS
ource Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
riority	Routine	·	
verride Auto Calculation Rule	No		212222
DA Received Date	04-Apr-2019	CTU Received Date	04-Apr-2019
TU Triage Date		CTU Data Entry Date	
leport Type	Spontaneous	Report Classification	Drug
ssign To	User		,
Iser/Group			
orward to Department	CDER (CDER-C	OSE-RSS-CTU@fda.hhs.gov) (E2B)	
ase Priority	Direct		
case First Name Reporter	Last Name	Email Address	Phone
(6) (6)	CATALON DE LA CA	(b) (6)	
Date the problem occurred  Serious  Did any of the following happer (Check all that apply)	Required help to prevent Disability or health pro	ent permanent harm oblem nt medical incident(Please Describe Below)	
Tell us what happened and h	low it happened (Inclu	ide as many details as possible F	DA may reach out to you t
STOLEN COLUMN CO		uul. I've never had a seizure before in	my life.
elevant Test/Laboratory Data Test Name		Test Date	1 of 1
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			- 1

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CTU No.: FDA-CDER-CTU-2019-01 (5) | Department: CTP | RCT No.: RCT (6) (6) | CTU Triage Date: 04-04-2019 | Total Pages: 5

M	idilional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ection C - About the Products				1 of 1
-	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Drug			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Yuul			
	Name of the company that makes (or compounds) the product				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmace Generic Biosimilar	y or an Outsourcing Facility		
	Strength		If Other		
	NDC number			-12	J 17 +
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Yes			
Dr	ug Therapy				1 of 1
1	Expiration date				
	Lot number				
	Dosage Form		2		111
-	Quantity		If Other		
	Frequency		If Other		1
	How was it taken or used	Respiratory (inhalation)	If Other		
	Date the person first started taking or using the product			*	
	Date the person stopped taking or using the product				
	Give best estimate of duration				

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Receipt No: RCT-(b) (6) \_\_\_\_\_ FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019 0 (6) | Department: CTP | RCT No.: RCT-(0) (6) | CTU Triage Date: 04-04-2019 | Total Pages:

	Is therapy still on-going?		
W	hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Ot	her identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
1	Serial Number		
	UDDI Number		
П	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	or implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	o Had the Problem	
	Person's Initials	With the second	
	Gender	Female	Ħ
	Age (specify unit of time for age)	20 Year(s)	Ħ
	Date of Birth		Ħ
	Weight	65.25 kg	Ħ
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

ase list all allergies (such	as to drugs, foods, pollen or others)	
Amoxicillin, Sulfa		
any other important info	mation about the person (such as smoking, pregr	nancy, alcohol use, etc.)
	edications and medical devices being used.	
Zoloft		
	ications and any vitamins, minerals, supplements	, and herbal remedies being use
	ications and any vitamins, minerals, supplements	, and herbal remedies being use
	ications and any vitamins, minerals, supplements	, and herbal remedies being use
	ications and any vitamins, minerals, supplements	, and herbal remedies being use
Vitamin D, Iron tion F - About the Persor	n Filling Out This Form	, and herbal remedies being use 1 of 1
vitamin D, Iron tion F - About the Person Primary?		
vitamin D, Iron tion F - About the Person Primary?	n Filling Out This Form	
/itamin D, Iron ion F - About the Persor Primary? Reporter is Patient?	n Filling Out This Form	
vitamin D, Iron  tion F - About the Persor  Primary?  Reporter is Patient?	n Filling Out This Form	
vitamin D, Iron tion F - About the Person Primary? Reporter is Patient? Title Last name	ı Filling Out This Form Yes	
vitamin D, Iron  tion F - About the Persor  Primary?  Reporter is Patient?  Title  Last name  Middle Name	ı Filling Out This Form Yes	
vitamin D, Iron  tion F - About the Persor  Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name	Filling Out This Form Yes	
vitamin D, Iron  tion F - About the Persor  Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street	Filling Out This Form Yes	
vitamin D, Iron  tion F - About the Persor  Primary?  Reporter is Patient?  Title  Last name  Widdle Name  First name  Number/Street	Filling Out This Form Yes	
vitamin D, Iron  tion F - About the Persor  Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street  City  State/Province	Filling Out This Form Yes	
tion F - About the Persor Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	Filling Out This Form Yes  (b) (6)	
vitamin D, Iron  tion F - About the Person  Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street  City  State/Province  Country  ZIP or Postal code	Filling Out This Form Yes  (b) (6)	
all over-the-counter med Vitamin D, Iron  tion F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address	Filling Out This Form Yes  (b) (6)	
tion F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address	Filling Out This Form Yes  (b) (6)	
tion F - About the Persor Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number	Filling Out This Form Yes  (b) (6)	

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Reporter Speciality

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (0) | Department: CTP | RCT No.; RCT-(0) (6) | CTU Triage Date: 04-04-2019 | Total Pages;
5

Today's date	04-Apr-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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CTU No.: FDA-CDER-CTU-2019-(6) | Department: CTP | RCT No.: RCT-(6) (6) | CTU Triage Date: 04-04-2019 | Total Pages:

All dates displayed in the report are in EST(GMT-05:00) time zone

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	- 1 A CO COM COLO 4 2 B A D	- 1 2 3 4 7 7 7 7 7 7 7
Override Auto Calculation Rule	No		
FDA Received Date	04-Apr-2019	CTU Received Date	04-Apr-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
Jser/Group			
Forward to Department	CDER (CDER-O	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct	3-1/(-1-)	
Contact			Annual Property of the Control of th
Case First Name Reporter	Last Name	Email Address	Phone
(b) (6)	(b) (6)	(b) (6)	(b) (6)
	0-1-0-1		
ection A - About the Problem			
What kind of problem was it?	Word hurt or had a had	side offset (including now or worsening sympto	me)
	Were hurt or had a bad side effect (including new or worsening symptoms)  Used a product incorrectly which could have or led to a problem		
(Check all that apply)			
	Used a product incorred		
	Used a product incorred Noticed a problem with	ctly which could have or led to a problem	
	Used a product incorred Noticed a problem with	ctly which could have or led to a problem the quality of the product	r
(Check all that apply)	Used a product incorred Noticed a problem with Had problems after swi	ctly which could have or led to a problem the quality of the product	r
(Check all that apply)  Date the problem occurred  Serious  Did any of the following happen?	Used a product incorrect Noticed a problem with Had problems after swith 17-Mar-2019  Yes	ctly which could have or led to a problem the quality of the product tching from one product maker to another make	r
(Check all that apply)  Date the problem occurred  Serious	Used a product incorrect Noticed a problem with Had problems after swith 17-Mar-2019  Yes  Hospitalization - admitted	ctly which could have or led to a problem the quality of the product tching from one product maker to another make	r
(Check all that apply)  Date the problem occurred  Serious  Did any of the following happen?	Used a product incorred Noticed a problem with Had problems after swi 17-Mar-2019 Yes Hospitalization - admitte	ctly which could have or led to a problem the quality of the product tching from one product maker to another make ed or stayed longer nt permanent harm	r
(Check all that apply)  Date the problem occurred  Serious  Did any of the following happen?	Used a product incorrect Noticed a problem with Had problems after swith 17-Mar-2019  Yes  Hospitalization - admitted	ctly which could have or led to a problem the quality of the product tching from one product maker to another make ed or stayed longer nt permanent harm	r
(Check all that apply)  Date the problem occurred  Serious  Did any of the following happen?	Used a product incorrect Noticed a problem with Had problems after swith 17-Mar-2019  Yes  Hospitalization - admitted Required help to preven Disability or health problems.	ctly which could have or led to a problem the quality of the product tching from one product maker to another make ed or stayed longer nt permanent harm	r
(Check all that apply)  Date the problem occurred  Serious  Did any of the following happen?	Used a product incorrect Noticed a problem with Had problems after swith 17-Mar-2019  Yes  Hospitalization - admitted Required help to preven Disability or health problems.	ctly which could have or led to a problem the quality of the product tching from one product maker to another make ed or stayed longer nt permanent harm	r

evant Test/Laboratory Data		+	1 of 1
Test Name	EEG	Test Date	03-Feb-2019
Test Result	Postive seizures	Test Unit	UNKNOWN
Low Test Range	7 seizures in 30 minutes	High Test Range	
More Information Available?			

I started having seizures to the point of breaking my hand. The seizures are getting worse and it is hard to stop using product.

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019-101 (6) | Department: CTP | RCT No.: RCT-10) (6) | CTU Triage Date: 04-04-2019 | Total Pages: 5

Additional Comments				
Section B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
Section C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Type	Drug/Biologic			
This report is about	Drug			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	luul			
Name of the company that makes (or compounds) the product	Juul			
Product Type(check all that apply)	Over-the-Counte	r a Pharmacy or an Outsourcing Facility		
Strength		If Other		
NDC number			-12	
Did the problem stop after the person reduced the dose or stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?	Yes			
Drug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product				
Date the person stopped taking or using the product				
Give best estimate of duration				

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Receipt No: RCT-(b) (6) \_\_\_\_\_ FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-00 (6) | Department: CTP | RCT No.: RCT-(0) (6) | CTU Triage Date: 04-04-2019 | Total Pages:

	Is therapy still on-going?		
W	hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Ot	her identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
1	Serial Number		
	UDDI Number		
П	Expiration date		
i	Was someone operating the medical device when the problem occurred?		
Fo	or implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	o Had the Problem	
	Person's Initials	O (C)	T
H	Gender	Female	
	Age (specify unit of time for age)	36 Year(s)	
	Date of Birth		
	Weight	87.75 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

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ase list all allergies (suc	h as to drugs, foods, pollen or others)	
Trazadone cipro		
t any other important inf	ormation about the person (such as smoking, pregnancy, alcohol use, etc.)	
t arry other important im	ormation about the person (such as smooting, pregnancy, alcohor use, etc.)	1
t all current prescription	medications and medical devices being used.	
Lexapro keppra abilify	modecations and modecat devices being asod.	
Lexapro Reppia ability		
t all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being	g used.
t all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being	g used.
t all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being	g used.
t all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being	g used.
t all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being	g used.
		g used.
ction F - About the Pers		g used.
ction F - About the Pers	on Filling Out This Form	
ction F - About the Perso Primary?	on Filling Out This Form	
ction F - About the Perso Primary? Reporter is Patient?	on Filling Out This Form	
ction F - About the Perso Primary? Reporter is Patient? Title	on Filling Out This Form  Yes	
ction F - About the Person Primary? Reporter is Patient? Title Last name	on Filling Out This Form  Yes	
ction F - About the Person Primary? Reporter is Patient? Title Last name Middle Name	on Filling Out This Form  Yes  (b) (6)	
ction F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name	on Filling Out This Form  Yes  (b) (6)  (b) (6)	
ction F - About the Personal Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	on Filling Out This Form  Yes  (b) (6)	
ction F - About the Personal Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	on Filling Out This Form  Yes  (b) (6)  (b) (6)	
ction F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	on Filling Out This Form  Yes  (b) (6)  (b) (6)  (b) (6)	
ction F - About the Personal Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	on Filling Out This Form  Yes  (b) (6)  (b) (6)  (b) (6)  USA	

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Reporter Organization

Reporter Speciality

Department

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (0) | Department: CTP | RCT No.; RCT-(0) (6) | CTU Triage Date: 04-04-2019 | Total Pages;
5

Today's date	04-Apr-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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ompany l	ails						
1-1	Unit	CDER-CTU	Originating Account	FAERS			
Source Me	dium	MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority		Routine					
Override A	uto Calculation Rule	No					
FDA Recei	ved Date	04-Apr-2019	CTU Received Date	04-Apr-2019			
CTU Triage Date Report Type			CTU Data Entry Date				
		Spontaneous	Report Classification	Drug			
Assign To		User					
Jser/Group	p						
orward to	Department	CDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)				
Case Prior	ity	Direct					
ontact	123127	3 32 7	2210				
Case	First Name	Last Name	Email Address	Phone			
Reporter	(b) (6)	(b) (6)	(b) (6)	(h) (6)			
Z	(b) (6)	(b) (6)	(b) (6)	(b) (6)			
Date the	e problem occurred	Had problems after switching from one product maker to another maker  10-Nov-2018					
Serious	E \$1000 AND 1000 AND	Yes					
	of the following happen? all that apply)	Required help to preven Disability or health problem Birth defect Life-threatening Death	nt permanent harm lem				
(Check	all that apply)	Required help to preven Disability or health problem Birth defect Life-threatening Death Other serious/important	nt permanent harm lem medical incident(Please Describe Below)	DA may reach out to you			
(Check	all that apply)	Required help to preven Disability or health problem Birth defect Life-threatening Death Other serious/important wit happened (Include	nt permanent harm lem	DA may reach out to you			
Tell us v ny addition My 17 y hospital vaping He has how les	what happened and ho onal documents if nece year old son who's been u lized for nicotine and drug - even as young as middle also started smoking ciga is harmful they are. This is	Required help to prevent Disability or health problem Birth defect Life-threatening Death Other serious/important with appened (Includessary)  sing/addicted to vaping wand addiction and has been a school age. My son is surettes. Completely agains an Epidemic for our your	medical incident(Please Describe Below)  de as many details as possible F  with Juul pods since Freshman year of to rehab twice since. We have never still addicted to nicotine and has need ast the marketing messages from Juul ung people and is a starting point for of	f high school had seizure. Wa seen so many young people ed the patch and gum to stop and other companies saying			
Tell us v ny addition My 17 y hospital vaping He has how less researce	what happened and ho onal documents if nece year old son who's been u- lized for nicotine and drug - even as young as middle also started smoking ciga is harmful they are. This is shed especially when deali	Required help to prevent Disability or health problem Birth defect Life-threatening Death Other serious/important with appened (Includessary)  sing/addicted to vaping wand addiction and has been a school age. My son is surettes. Completely agains an Epidemic for our your	medical incident(Please Describe Below)  de as many details as possible F  with Juul pods since Freshman year of to rehab twice since. We have never still addicted to nicotine and has need ast the marketing messages from Juul ung people and is a starting point for or	f high school had seizure. Wa seen so many young people ed the patch and gum to stop and other companies saying other drugs. This needs to be			
Tell us v ny addition My 17 y hospital vaping He has how less researce	what happened and ho onal documents if nece year old son who's been u lized for nicotine and drug - even as young as middle also started smoking ciga is harmful they are. This is	Required help to prevent Disability or health problem Birth defect Life-threatening Death Other serious/important with appened (Includessary)  sing/addicted to vaping wand addiction and has been a school age. My son is surettes. Completely agains an Epidemic for our your	medical incident(Please Describe Below)  de as many details as possible F  with Juul pods since Freshman year of to rehab twice since. We have never still addicted to nicotine and has need ast the marketing messages from Juul ung people and is a starting point for or	f high school had seizure. Wo seen so many young people ed the patch and gum to stop and other companies saying			

elevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	<u>,                                    </u>
More Information Available?		

CTU No.: FDA-CDER-CTU-2019 (6) | Department: CTP | RCT No.: RCT-(9) (6) | CTU Triage Date: 04-04-2019 | Total Pages: 5

A	dditional Comments				
S	ection B - Product Availability	-			
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
S	ection C - About the Products				1 of 1
	Suspect	Yes			
H	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Drug			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Juul pods for vaping			
	Name of the company that makes (or compounds) the product	Juul			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Di	rug Therapy				1 of 1
2	Expiration date				
	Lot number				
	Dosage Form				
-	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Respiratory (inhalation)	If Other		
	Date the person first started taking or using the product			-	
	Date the person stopped taking or using the product				
	Give best estimate of duration	2 Year			

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Receipt No: RCT-(b) (6) FDA 3500B Form

CTU No.; FDA-CDER-CTU-2019-0) (6 | Department: CTP | RCT No.; RCT-(0) (6) | CTU Triage Date: 04-04-2019 | Total Pages:

Is therapy still on-going?	Yes	
Why was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
Recreational		
Returned to Manufacturer On		
Section D - About the Medical De	evice	
Name of medical device		
Name of the company that makes the medical device		
Other identifying information (The locate them)	model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
Model Number		
Catalog Number		
Lot Number		
Serial Number		
UDDI Number		
Expiration date		
Was someone operating the medical device when the problem occurred?		
For implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
Date the implant was put in	Date the implant was taken out (If relevant)	
Section E - About the Person Wh	o Had the Problem	
Person's Initials	Unspecified	
Gender	Male	
Age (specify unit of time for age)	17 Year(s)	
Date of Birth		
Weight		
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

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PI	ease list all allergies (such	as to drugs, foods, pollen or others)	
Lis	st any other important infor	mation about the person (such as smoking, pregnancy, alcohol use, etc.)	
	Minor under age of 18		
Lis	st all current prescription m	edications and medical devices being used.	
Lis	st all over-the-counter med	ications and any vitamins, minerals, supplements, and herbal remedies being use	d.
Se	ection F - About the Person	Filling Out This Form 1 of	
Se	ection F - About the Persor	Filling Out This Form 1 of Yes	
Se	ection F - About the Persor Primary? Reporter is Patient?		
Se	Primary?		
Se	Primary? Reporter is Patient?	Yes	
Se	Primary? Reporter is Patient? Title		
Se	Primary?  Reporter is Patient?  Title  Last name	Yes	
Se	Primary? Reporter is Patient? Title Last name Middle Name	Yes (b) (6)	
Se	Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name	Yes (b) (6)	
Se	Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street	Yes (b) (6) (b) (6)	
Se	Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street  City	Yes (b) (6) (b) (6)	
Se	Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street  City  State/Province	(b) (6) (b) (6) (b) (6)	
Se	Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street  City  State/Province  Country	Yes (b) (6) (b) (6) (b) (6) (b) (6) USA	
Se	Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street  City  State/Province  Country  ZIP or Postal code	Yes  (b) (6)  (b) (6)  (b) (6)  USA	
Se	Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street  City  State/Province  Country  ZIP or Postal code  Telephone number	Yes  (b) (6)  (b) (6)  (b) (6)  USA  (b) (6)	
Se	Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street  City  State/Province  Country  ZIP or Postal code  Telephone number  Email address	Yes  (b) (6)  (b) (6)  (b) (6)  USA  (b) (6)	
Se	Primary?  Reporter is Patient?  Title  Last name  Middle Name  First name  Number/Street  City  State/Province  Country  ZIP or Postal code  Telephone number  Email address  Fax	Yes  (b) (6)  (b) (6)  (b) (6)  USA  (b) (6)	

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CTU No.: FDA-CDER-CTU-2019-101 (6) | Department: CTP | RCT No.: RCT-10) (6) | CTU Triage Date: 04-04-2019 | Total Pages: 5

Today's date	04-Apr-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

Generated by: SYSTEM 04-Apr-2019 11:45:49 Page 5 of 5 Generated on:

CTU No.: FDA-CDER-CTU-2019-01.05 | Department: CTP | RCT No.: RCT-0 (6) | CTU Triage Date: 04-04-2019 | Total Pages:

All dates displayed in the report are in EST(GMT-05:00) time zone

Contact

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		*
Override Auto Calculation Rule	No		4,000
FDA Received Date	04-Apr-2019	CTU Received Date	04-Apr-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		1,
User/Group			
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

- Sitted St				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (b)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem			
	nd of problem was it? all that apply)	Used a product incorrectly w	effect (including new or worsening sympto which could have or led to a problem quality of the product g from one product maker to another make	

Date the problem occurred

Serious

Did any of the following happen?
(Check all that apply)

Hospitalization - admitted or stayed longer
Required help to prevent permanent harm
Disability or health problem
Birth defect
Life-threatening

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Other serious/important medical incident(Please Describe Below)

Death

My fifteen year old daughter used an e-cigarette (Jul). Immediately after use, she convulsed, passed out, and was incontinent. She was taken to ER by ambulance. Her heart raced out of control and she was given fourteen units of Ativan over the course of about ten to twelve hours because her heart rate was out of control, running from 145 - 155 bpm. Her blood tests showed negative for any illegal drugs. It is not known if the product was spiked with a street drug of some sort. Tests showed negative, but ER staff suspected spiking of some sort. She was on a treatment of Wellbutrin that might have contributed to the reaction. She was treated at St. Agnus Medical Center in Fresno. I filed a police report with Fresno PD, but nothing really came of it. St. Agnus MC should have the tests on file.

elevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	

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	More Information Available?		
Αd	dditional Comments		
	I believe the product is still in the p	ossession of (b) (6)	
Se	ection B - Product Availability		
	Do you still have the product in case we need to evaluate it?	No	
	Do you have a picture of the product? (check yes if you are including a picture)	No	
Se	ection C - About the Products		1 of 1
	Suspect	Yes	
	Primary?	Yes	
	Туре	Drug/Biologic	411
	This report is about		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	e-cigarette (Suorin)	
	Name of the company that makes (or compounds) the product	I believe if is Suorin	
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar	
	Strength	If Other	
	NDC number		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?		
	Did the problem return if the person started taking or using the product again?		
Dr	ug Therapy		1 of 1
1	Expiration date		14
	Lot number	Unknown	
	Dosage Form		
1-1	Quantity	If Other	
	Frequency	If Other	1
	How was it taken or used	If Other	
	Date the person first started taking or using the product		
	Date the person stopped taking		

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Receipt No: RCT-285025 FDA 3500B Form

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	Give best estimate of duration		1
	Is therapy still on-going?		Ī
W	hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
L			
	Returned to Manufacturer On		Ī
0.	ection D - About the Medical De		
30	Name of medical device	evice	
H	Name of the company that		
	makes the medical device		
	ther identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
IIO	cate them)		
i	Model Number		
ī	Catalog Number		Ì,
T	Lot Number		Ī
П	Serial Number		Ī
Ħ	UDDI Number		
ī	Expiration date		Ī
ī	Was someone operating the		ī
	medical device when the problem occurred?		
		NLY (such as pacemakers, breast implants, etc.)	
	ate the implant was put in	Date the implant was taken out (If	
	ate the implant was put in	relevant)	
Se	ection E - About the Person Wh	to Had the Problem	
Code	Person's Initials	(D) (B)	
	Gender	Female	F
ī	Age (specify unit of time for age)	15 Year(s)	ī
	Date of Birth		ī
	Weight	49.5 kg	ī
	Ethnicity (Choose only one)	Not Hispanic/Latino	Ī
	Race (Check all that apply)	American Indian or Alaskan Native	7
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	

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

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ease list all allergies (suc	h as to drugs, foods, pollen or others)	
Pollen		
t any other important info	ormation about the person (such as smoking, pregnancy, alcohol use, etc.)	
any other important into	offilation about the person (such as smoking, pregnancy, alcohol use, etc.)	-
	medications and medical devices being used.	- 4
300 mg Wellbutrin. Since in	ncident, stopped taking.	
t all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being o	used.
Benadryl Zvertec		
Benadryl, Zyertec		
	on Filling Out This Form	
ction F - About the Perso		of 1
ction F - About the Perso Primary?	on Filling Out This Form 1	
ction F - About the Perso Primary? Reporter is Patient?		
ction F - About the Perso Primary? Reporter is Patient? Title	Yes	
ction F - About the Perso Primary? Reporter is Patient? Title Last name		
ction F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name	Yes (b) (6)	
ction F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name	Yes (b) (6)	
ction F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name	Yes (b) (6)	
ction F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City	Yes (b) (6)	
ction F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	Yes (b) (6) (c) (d) (d) (e) (e) (e) (e) (e) (e) (e) (e) (e) (e	
ction F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City	Yes (b) (6) (c) (d) (d) (e) (e) (e) (e) (e) (e) (e) (e) (e) (e	
ction F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	Yes  (b) (6)  (b) (6)  (b) (6)	
ction F - About the Person Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	Yes  (b) (6)  (b) (6)  (b) (6)	

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Reporter Organization

Reporter Speciality

Department

CTU No.: FDA-CDER-CTU-2019 (6) Department: CTP | RCT No.: RCT-(D) (B) | CTU Triage Date: 04-04-2019 | Total Pages.

Today's date	04-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 04-Apr-2019 11:45:43 Page 5 of 5 MedWatch 3500B Consumer/Patient Report

The FDA Safety Information and Adverse Event Reporting Program

FDA Safety Report ID #	FDA Received Date	03-Apr-2019	
		·	
SECTION A - ABOUT THE PROBLEM			
	Were hurt or had a bad side effect (including new or worsening symptoms)  Used a product incorrectly which	Yes	
11. What kind of problem was it?	could have or led to a problem		
The Macking of problem was it.	Noticed a problem with the quality of the product		
	Had problems after switching from one product maker to another maker		
	Hospitalization - admitted or stayed longer	Yes	
	Required help to prevent permanent harm		
	Disability or health problem	Yes	
2. Did any of the following happen?	Birth defect		
	Life-threatening		
	Death (include date)		
	Other serious/important medical incidents (please describe)	Yes	Grand mal seizures
3. Date the problem occurred:	09-Mar-2016	<u> </u>	'

A4. Tell us what happened and how it happened:

[A4. Tell us what happened and how it happened:

[A4. Tell us what happened and how it happened:

[A4. Tell us what happened and how it happened:

[A4. Tell us what happened and will be seeing my neurologic within the next few weeks to docuse another two situations that sectures may have occurred. I am assuming that these two instances are solitures with one not being a grant and secture (my security to be and or in the control properties and selectors.) I grant that we creditly. I am created properties with selecting should be seeing a grant and secture in the selection between dispersed and selectors. I graduated high school in 10 and not be code of queetes sharing list high section is the control of the selection between dispersed and selectors. I graduated high school in 10 and not be code of queetes sharing list high ETEGS on with high section in the control may be common the selection of the

CTU No.: FDA-CDER-CTU-2019-10) (6) Department: CTP | RCT No.: RCT-10) (6) CTU Triage Date: 04-04-2019 | Total Pages: 10

A5. Relevant Tests/Laboratory Data:		
Test 1		
Test Date:	12-Oct-2018	
	EEG	
Test Name:		
Tost (value.		
	Genetic epilepsy	
Test Result:		
Test Unit:		
Low Test Range:		
High Test Range:		
Test 2		
Test Date:		
Test Name:		
Test Result:		
Test Unit:		
Low Test Range:		
High Test Range:		
Test 3		
Test Date:		
1001 Date.		
And Address of the Control of the Co		
Test Name:		
Test Result:		
Test Result:		
Test Unit:		
Low Test Range:		
High Test Range:		
Test 4		
Test Date:		
Test Name:		
Tool Hallo.		
1		
Test Result:	* 1 H	
Test Helle		
Test Unit:		
Low Test Range:		
High Test Range:		

CTU No.: FDA-CDER-CTU-2019-10 (6) | Department: CTP | RCT No.: RCT-10 (6) | CTU Triage Date: 04-04-2019 | Total Pages: 10

Test Name:  Test Name:  Test Name:  Test Stage:  Test Stage: Test Stage: Test Stage: Test Stage: Test Stage:	A5. Relevant Tests/Laboratory Data:				
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Low Test Range:	Tost Unit:				
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	Trigit rest Kaliye.				

AF A LUC LO		
A5. Additional Comments:		
	15.11	1
Please select the cause of the problem that	Problem with a product	Yes
applies below:	Problem with a device	Yes
SECTION B - PRODUCT AVAILABILITY		
B1. Do you still have the product in case we need to	No	
evaluate it?		

B2. Do you have a picture of the product?

SECTION C - ABOUT THE PRODUCTS			
Product 1	-		
C1. This report is about	Drug Cosmetic, Dietary Supplement or Food/Medical Food		
C2. Name(s) of the product as it appears on the box, bottle, or package:	1) E-cigarettes	į.	
C3. Check if therapy is on-going	0		
C4. Name(s) of the company that makes (or compounds) the product:			
	OTC (Over-the-counter)		
C5. Product Type:	Compounded	Yes	
ov. Froudet Type.	Generic		
	Biosimilar		
C6. Expiration date:			
C7. Lot number:			
C8. NDC number:			
C9. Strength:			
C10. Quantity:			
C11. Frequency:			
C12. How was it taken or used?	Taken by mouth		
C13a. Date the person first started taking or using the product:			
C13b. Date the person stopped taking or using the product:			
C14. Give best estimate of duration:			
C15. Why was the person using the product?			
C16. Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
C17. Did the problem return if the person started taking or using the product again?	Didn't restart		

SECTION C - ABOUT THE PRODUCTS		
Product 2		
C1. This report is about	Drug  Cosmetic, Dietary Supplement or Food/Medical Food	
C2. Name(s) of the product as it appears on the box, bottle, or package:		
C3. Check if therapy is on-going		
C4. Name(s) of the company that makes (or compounds) the product:		
	OTC (Over-the-counter)	
C5. Product Type:	Compounded	
os. Froduct Type.	Generic	
	Biosimilar	
C6. Expiration date:		
C7. Lot number:		
C8. NDC number:		
C9. Strength:		
C10. Quantity:		
C11. Frequency:	·	
C12. How was it taken or used?		
C13a. Date the person first started taking or using the product:		
C13b. Date the person stopped taking or using the product:		
C14. Give best estimate of duration:		
C15. Why was the person using the product?		
C16. Did the problem stop after the person reduced the dose or stopped taking or using the product?		
C17. Did the problem return if the person started taking or using the product again?		

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SECTION D - ABOUT THE MEDICAL DEVICE	
D1. Name of medical device:	Medical "[INVALID] for rotator cuff and labrum
D2. Name of the company that makes the medical device:	not sure
D3. Model number:	
D4. Catalog number:	
D5. Lot number:	
D6. Serial number:	
D7. UDI number:	
D8. Expiration date:	
D9. Was someone operating the medical device when the problem occurred?	No
	The person who had the problem
D9. If yes, who was operating it?	A health professional (such as a doctor, nurse, or aide)
	Someone else (Please explain who) :
D10. Date the implant was put in:	
D10. Date the implant was taken out:	

SECTION E - ABOUT THE PERSON WHO HAD T	HE PROBLEM	
E1. Person's Initials:	NRF	
	Female	
	Male	Yes
E2. Gender:	Intersex	
	Transgender	
	Prefer not to disclose	
E3. Age:	4	
E4. Date of Birth:	(b) (6)	
E5. Weight:	. 140	. lb
EC FALLER.	Hispanic/Latino	
E6. Ethnicity:	Not Hispanic/Latino	Yes
	Asian	
	American Indian or Alaskan Native	
4.5-4	Black or African American	-
E7. Race:	White	Yes
	Native Hawaiian or Other Pacific Islander	

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10				

E8. List known medical conditions:	
Epilepsy, adhd, severe anxiety and depression	
E9. Please list all allergies:	
None known	
E10. List any other important information about the person:	
weed consumption, rare alcohol use, nicotine	

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E11. List all current prescription medications and medical devices being used:	
Kepre, Lamictal, trazodone, adderall, sertraline,	
E12. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used:	
none	

SECTION F - ABOUT THE PERSON FILLING OUT THIS F	FORM
F1. Last Name	(D)(6)
F2. First Name	1010
F3. Number/Street	(b) (6)
F4. City and State/Province	(b) (6)
F5. ZIP or Postal Code	to 18
F6. Country	US
F7. Telephone number	(b) (6)
F8. Email address	(b) (6)
F9. Today's date	03-Apr-2019
F10. Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
F11. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box (Confidentiality Requested):	Yes

Low Test Range

Basic Detail	S				
Company Un	it	CDER-CTU	Originating Account	FAERS	
Source Medic	um	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority		Routine			
Override Auto	o Calculation Rule	No			
FDA Receive	ed Date	04-Apr-2019	CTU Received Date	04-Apr-2019	
CTU Triage [	Date		CTU Data Entry Date		
Report Type		Spontaneous	Report Classification	Drug	
Assign To		User			
User/Group					
Forward to D	epartment	CDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority		Direct	3		
Contact Case Reporter	First Name	Last Name	Email Address	Phone	
Image: Control of the	(b) (b)	(b) (6)	(b) (6)	(b) (6)	
	f the following happen? I that apply)	Yes  Hospitalization - admitted or stayed longer Required help to prevent permanent harm			
		Disability or health problems Birth defect Life-threatening Death			
Other seri	ious/important medical Please Describe Below)	Increase in seizure ac			
incident(P			le as many details as possible	FDA may reach out to you fo	
incident(P Tell us whany addition In relation in the office	at happened and how all documents if nece to the link between vap be who openly vape thro Our office atmosphere is	ssary) ing and seizures, I was ughout the day. Having	de as many details as possible diagnosed with epilepsy in 2007 an surgery to correct my condition I se smoke. I do have a concern, as th	d recently have vaping coworkers emed to be seizure free until	
incident(P Tell us wh iny addition In relation in the offic recently. ( my career	at happened and how all documents if nece to the link between vap be who openly vape thro Our office atmosphere is	ssary) ing and seizures, I was ughout the day. Having	diagnosed with epilepsy in 2007 an surgery to correct my condition I se	d recently have vaping coworkers emed to be seizure free until	
incident(P Tell us wh any addition In relation in the offic recently. ( my career	at happened and hovel all documents if neces to the link between vapore who openly vape through office atmosphere is really above.	ssary) ing and seizures, I was ughout the day. Having	diagnosed with epilepsy in 2007 an surgery to correct my condition I se	d recently have vaping coworkers emed to be seizure free until is will have a detrimental effect o	

High Test Range

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CTU No.: FDA-CDER-CTU-2019 (6) | Department: CTP | RCT No.: RCT-(9) (6) | CTU Triage Date: 04-04-2019 | Total Pages;
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	More Information Available?					
A	dditional Comments					
S	ection B - Product Availability					
	Do you still have the product in case we need to evaluate it?					
	Do you have a picture of the product? (check yes if you are including a picture)	No				
Se	ection C - About the Products					1 of 1
	Suspect	Yes				
	Primary?	Yes				
	Туре	Drug/Biologic				
	This report is about					
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Vaping products				
	Name of the company that makes (or compounds) the product	Vaping products				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Generic Biosimilar	a Pharmacy or an Out	sourcing Facility		
	Strength		If Oth	er		
	NDC number					
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No				
	Did the problem return if the person started taking or using the product again?					
Di	rug Therapy					1 of 1
	Expiration date					- 4
	Lot number					
	Dosage Form					
	Quantity		If Oth	er		
	Frequency		If Oth	er		
	How was it taken or used	-	If Oth	er	14	
	Date the person first started taking or using the product  Date the person stopped taking or using the product		·			

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Receipt No: RCT-(b) (6) FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-01 (6) | Department: CTP | RCT No.: RCT-01 (6) | CTU Triage Date: 04-04-2019 | Total Pages:

	Give best estimate of duration		
П	Is therapy still on-going?		
W	ny was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		П
	Name of the company that		П
-	makes the medical device		
Ot	her identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	111 -		
H	Model Number		H
	Catalog Number		Ė
	Lot Number		Ħ
	Serial Number		
	UDDI Number		П
	Expiration date		
	Was someone operating the		П
	medical device when the problem occurred?		
		NLY (such as pacemakers, breast implants, etc.)	
D.	ate the implant was put in	Date the implant was taken out (If relevant)	
56	ction E - About the Person Wh	io Had the Problem	
	Person's Initials	Do-La	
	Gender	Male	H
	Age (specify unit of time for age)	42 Year(s)	H
	Date of Birth		
	Weight	98.55 kg	H
	Ethnicity (Choose only one)	Not Hispanic/Latino	H
	Race (Check all that apply)	American Indian or Alaskan Native	П
		Native Hawaiian or Other Pacific Islander	
		Asian	
	1	White	
		Black or African American	

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

	Epilepsy	
ΙĐΙ	ease list all allergies (such as to drugs, foods, pollen or others)	
	None	
Lis	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medications and medical devices being used.	
	Trileptal, oxcarbazipene, lamotrigene, briviact	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	B-12	
0	ection E - About the Person Filling Out This Form	

tion F - About the Persor	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (5)	
Middle Name		
First name	(b) (5)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(b) (c)	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
ax		
Reporter Organization		
Department		
Reporter Speciality		

Generated by: SYSTEM Generated on: 04-Apr-2019 08:15:30 Page 4 of 5

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (6) | Department: CTP | RCT No.; RCT (6) (6) | CTU Triage Date: 04-04-2019 | Total Pages;
5

Today's date	04-Apr-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

Generated by: SYSTEM 04-Apr-2019 08:15:30 Page 5 of 5 Generated on:



#### REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-06

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Organization Name <br/> <br/>

Confirm Email (b) (6)

First Name (b) (6)

Last Name (b) (6)

Did you report the problem to the manufacturer?

Job Title <br/>
<b

Phone

Email (If prefilled, changing this email address will not change your Login email ID)

(b) (6)

**Country** United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned
Citizen Type (select all that

apply)

Concerned citizen

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

<blank>

# **Problem Summary**

Problem Start Date 03/01/2019

Problem End Date 03/30/2019

**Please describe the health** My son had to separate seizures on two separate incidents after vaping **problem or product problem.** nicotine

The Attachments page will accept uploads of any records, pictures, or other information.

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

Life threatening

or more)

Treatment Received (select all that apply)

Self-Treated

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

<blank>

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

Select Unit of Time

minute(s)

What is the current status of the health problem?

Recovered or Resolved

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a Us separate report for each affected person, if possible.)

User(s)

How many users were

1

affected? Gender

Male

Race (Select all that apply)

<blank>

**Ethnicity** 

Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the

problem occurred

14

Select Unit of Age

year(s)

Please list any known preexisting health problems for Type 1 diabetes, seizures

the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Insulin

# What are the main symptoms or health problems?

Term describing the health problem

Seizure

# **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** 

e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** <blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown

When did the person purchase this product?

<blank>

**UNIVERSAL PRODUCT** CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol? <a href="https://doi.org/10.1001/journal.org/">blank></a>

Any other identifying tobacco product codes (for example, SKU, item/catalog <br/>number, manufacturing date/ batch code) <br/>

How was this product acquired? <br/>

Do you know where the product was purchased? <black</pre>

Manufacturer Name <br/> <br/>

# **Tobacco Product Packaging and Portions**

**Manufacturer Investigation Information** 

**Tobacco Product Purchase Location** 

**Tobacco Product Manufacturer Information** 

# **Tobacco Product Use Details**

How was the tobacco product used?	<blank></blank>
On average, how often is this tobacco product used?	<blank></blank>
Are other substances being mixed in with the tobacco product when used?	<blank></blank>
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	6
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the problem occur?	5
Select Unit of Measure	Minute(s)
How long has the person been using this particular brand or label?	<blank></blank>
Select Unit of Measure	<blank></blank>
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	<blank></blank>

# **Tobacco Product Parts**

## **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

## **Other Tobacco Products**

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

E-cigs cause seizures

#### **Attached Files**

None



#### REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-06

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

## **Contact Information - Sender**

Organization Name <blank>

Confirm Email (b) (6)

First Name

Last Name (b) (6

Did you report the problem to the manufacturer?

to the mandacturer.

Phone (b) (6)

Email (If prefilled, changing this email address will not change your Login email ID)

Job Title

(b) (6)

Country United States

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

City/Town <br/> <blank>

State (b) (6)

ZIP/Postal Code <br/>
<b

Sender Category Consumer/Concerned Citizen (FdaTPR)

<blank>

Consumer/Concerned

Citizen Type (select all that Consumer

apply)

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

Yes

# **Problem Summary**

Problem Start Date 11/26/2017

Problem End Date <br/>
<

Please describe the health problem or product problem.

Seizures from vaping, specifically Juul

The Attachments page will accept uploads of any records, pictures, or other information.

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

Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Multiple MRI's, EEG, Blood work, Cat Scan

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

Not Recovered or Unresolved

## Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

Female

Gender

No

Pregnant

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem

Race (Select all that apply)

(b) (6)

Age of the person when the problem occurred

22

Select Unit of Age

year(s)

Please list any known preexisting health problems for Hypothyroidism the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Tirosint for thyroid

# What are the main symptoms or health problems?

Term describing the health problem

Seizure grand mal

## **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping Rechargeable product product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

Purchased in a non-refillable disposable cartridge

electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Tobacco, Menthol, Mint (such as wintergreen or spearmint), Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

10/03/2017

UNIVERSAL PRODUCT CODE (UPC) from Label

081991301158

Does the involved product device or package bear the "UL" symbol?

No

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

United States

Where is the tobacco product now?

Product was discarded

How was this product acquired?

In a Store

Do you know where the product was purchased?

<blank>

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

## **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

No

On average, how often is this tobacco product used? Every Day

Are other substances being mixed in with the tobacco

product when used?

Did the problem occur with

first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

Select Unit of Measure Year(s)

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

Select Unit of Measure Month(s)

How long has the person been using this particular brand or label?

1

2

Select Unit of Measure Year(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

**Full Tobacco Product Part** Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

**Tobacco Product Part Type** 

Battery(reusable)

When was this tobacco product part purchased or acquired?

10/03/2017

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Any other identifying tobacco product part codes(e.g. SKU, item/catalog number)

<blank>

What is the country of manufacture of the tobacco product part?

United States

Where is the tobacco product part now?

Product was discarded

Do you know who manufactured this tobacco product part?

#### **Tobacco Product Part Purchase Location**

How was this tobacco product part acquired?

In a Store

**Purchase Location Name** 

<blank>

Country

United States

Phone

<blank>

Street Address Line 1

<blank>

Street Address Line 2

<blank>

City/Town

<blank>

State

<blank>

ZIP/Postal Code

<blank>

Web Address

<blank>

**Email Address** 

<blank>

## **Tobacco Product Part Manufacturer Information**

State <br/> <blank>

State/Province <blank>

## **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

## **Other Tobacco Products**

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

Since using the Juul, myself, the user have experienced multiple seizures. I have been treated for them by medical professionals but they can not seem to find the problem as to what is causing them.

## **Attached Files**

None



## REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-06

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Organization Name

Confirm Email

First Name

Last Name

Did you report the problem to the manufacturer?

Job Title

(b) (6)

No

No

Email (If prefilled, changing this email address will not change your Login email ID)

Phone

(b) (6)

Country United States

Street Address Line 1 (b) (6)

Street Address Line 2

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that

apply)

Consumer

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

Yes

# **Problem Summary**

Problem Start Date 04/01/2019
Problem End Date 04/01/2019

**Please describe the health** Had a seizure 4/1/19 around 8am lasted two minutes long. Started **problem or product problem.** vaping about 8 months ago using Nic salts.

The Attachments page will accept uploads of any records, pictures, or other information.

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

Lasting disability or other permanent health problem

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

lifetime on anti seizure medicine

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

## Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender

Male

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

26

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

Migranes

# **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Propanalol 80 mg ER. Maxalt 10mg as needed. max 10 our month

# What are the main symptoms or health problems?

Term describing the health problem

Other

## **Tobacco Products**

**Tobacco Product Type** 

Other

Description of other tobacco

product type

<blank>

**Tobacco Product Subtype** 

<blank>

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic

<blank>

waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

<blank>

electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the <blank> following? (select all that apply) Was the e-liquid dripped on to the atomizer or heating <blank> element? Full Tobacco Product Name, including Brand and Sub-Smok Nord with 25mg nicotine levels pachy mama liquid Brand (if unknown, please enter "unknown") When did the person 09/01/2018 purchase this product? UNIVERSAL PRODUCT <blank> CODE (UPC) from Label Does the involved product device or package bear the <blank> "UL" symbol? Any other identifying tobacco product codes (for example, SKU, item/catalog <blank> number, manufacturing date/ batch code) What is the country of manufacture of the tobacco China product? Where is the tobacco <blank> product now? How was this product <blank> acquired? Do you know where the <blank> product was purchased?

## **Tobacco Product Packaging and Portions**

<blank>

Manufacturer Name

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

Select Unit of Measure

Month(s)

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

Select Unit of Measure

Month(s)

How long has the person been using this particular brand or label?

Select Unit of Measure

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

## **Other Tobacco Products**

**Tobacco Product Type** 

Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Marlboro gold shorts

Is the tobacco product currently being used?

No

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

I saw the report about seizures being linked to vaping and on 3/31/19 I had one without any prior history of seizures.

## **Attached Files**

FILENAME IMG\_4329.jpeg

**Description of Attachment** hospitasl paperwork

Attachment Type Laboratory Report



#### REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-06

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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



Regulatory Status Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

# Did you report this problem somewhere else (outside SRP)?

Yes

# Describe who the problem was reported to

A seizure was reported to medical professionals following an incident that resulted in a traffic accident. Multiple seizures have been experienced. The individual has received medical care and diagnosis. CAT scans have found no known issue that would cause the seizures. The 18 year old patient frequently Vapes & has been using since approximately the age of 16. The patient is now being treated with antiseizure medication. I am not the affected individual however, I was the legal guardian of the individual until his 18th birthday.

#### Contact Information - Sender

Confirm Email

**First Name** 

**Last Name** 

Phone

Email (If prefilled, changing this email address will not change your Login email ID)

Country

**United States** 

Street Address Line 1

b) (6)

City/Town

State

ZIP/Postal Code

Sender Category

Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that

apply)

Concerned citizen

## **Problem Summary**

**Problem Start Date** 01/19/2019

Problem End Date 02/08/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

A seizure occurred that resulted in a traffic accident. The patient was treated for minor injuries following a CAT scan to diagnose the source of the seizure with no defect found. The individual was referred to a neurologist for treatment and is currently on anti-seizure medication. The individual is a frequently vapes and has been a user since approximately 16 years of age.

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

Needed treatment to prevent permanent harm

Treatment Received (select

all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

The individual was seen in the emergency room for minor injuries following an accident that resulted from a seizure while driving. The emergency room ran a CAT scan to determine any brain injury and referred the individual to a neurologist for treatment. The individual had experienced multiple seizures prior to the incident that resulted in an accident and is currently being treated with anti-seizure medication. Further medical information would be made available upon request with the consent of the individual, involved.

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

Select Unit of Time

year(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Male

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

18

Select Unit of Age

year(s)

Please list any known preexisting health problems for None the affected person

# **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

None

# What are the main symptoms or health problems?

Term describing the health problem

Partial seizures with secondary generalization

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Mint (such as wintergreen or spearmint)

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

01/10/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product acquired?

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

**Manufacturer Investigation Information** 

#### **Tobacco Product Purchase Location**

Purchase Location Name Vape store

Country United States

Phone <br/>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <br/> <blank>

State Colorado

ZIP/Postal Code 81507

Web Address <br/> <br/>

Email Address <br/> <blank>

#### **Tobacco Product Manufacturer Information**

# **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

On average, how often is this tobacco product used? Every Day

Are other substances being mixed in with the tobacco No

product when used?

Did the problem occur with first time use of the tobacco

product?

No

How long has the person been using this type of tobacco product?

3

Select Unit of Measure Year(s)

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

Select Unit of Measure Hour(s)

How long has the person been using this particular brand or label?

1

Select Unit of Measure Year(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after Yes repeat use of the tobacco product?

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

#### **Tobacco Product Parts**

Other Products Used

**Other Tobacco Products** 

Additional Information

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-07

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	        
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	   
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	(b) (b)
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Mother

# **Problem Summary**

Problem Start Date 02/02/2019

Problem End Date 04/06/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

My daughter who is epileptic and already prone to seizures has been vaping since December. We have seen an increase in her seizure activity in the last few weeks. Her father and I advised her to stop vaping immediately and explained to her the reason we suggested it. She did acknowledge that her seizures have been worse lately.

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

None of the above

Treatment Received (select all that apply)

None

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

<blank>

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Female

Pregnant

No

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

23

Select Unit of Age

year(s)

Please list any known preexisting health problems for Epilepsy the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Kepler Lamictal

# What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

<blank>

Full Tobacco Product Name, including Brand and Sub-

Voopoo DRAG

Brand (if unknown, please enter "unknown")

When did the person purchase this product?

02/02/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the

Don't Know

"UL" symbol?

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco product?

China

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

<blank>

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

#### **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location Name** 

Sunny's smoke shop

Country

United States

Phone (979) 559-7531

Street Address Line 1 42 Washington St.

Street Address Line 2 <blank>

City/Town Gloucester

State Massachusetts

ZIP/Postal Code 01930

Web Address <blank>

**Email Address** <blank>

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is Some Days this tobacco product used?

Are other substances being mixed in with the tobacco product when used?

Describe what substances are being mixed with the

tobacco product

<blank>

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

Select Unit of Measure Month(s)

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

<blank>

Select Unit of Measure

<blank>

How long has the person been using this particular brand or label?

2

Select Unit of Measure

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

#### **Other Tobacco Products**

**Tobacco Product Type** 

Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

Every Day

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-07

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

(b) (6)

Create a name to help you find this report in the future

(max length: 50 characters)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

#### Contact Information - Sender

Organization Name

Confirm Email

First Name

Last Name

Did you report the problem to the manufacturer?

Job Title

Phone

Email (If prefilled, changing this email address will not change your Login email ID)

Country United States

Street Address Line 1 <blank>
Street Address Line 2 <blank>
City/Town <br/>
<br/>
<br/>
City/Town <br/>
<br/

State (b) (6)

ZIP/Postal Code <blank>

Sender Category Healthcare Professional (FdaTPR)

Healthcare Professional type Physician

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

No

Describe your relationship to the person who experienced the health problem

attending physician

#### **Problem Summary**

Problem Start Date <br/>

Problem End Date

<blank>

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Patient states he vaped "5-6 snaps" on March 31, 2019. Felt a little off, went to take elevator, and lost consciousness, lost urinary continence, found himself on the floor, nose bleeding, bump on nose and bump on back of head from falling and perhaps hitting a desk that was in the hallway. April 1st he was still groggy, diagnosed with mild concussion. Told to rest. Rested until April 3rd, when he vaped "2-3 snaps" again, went to the mall, and fell twice within half an hour, losing consciousness and urinary continence again. These two were witnessed, and "jerking motions" were noted. Admitted to hospital where he was fine, nothing was noted on neuro exam, we recommended he restrain from vaping, and do an outpatient EEG.

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

Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

No imaging was done, EEG is pending.

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

4

Select Unit of Time

day(s)

What is the current status of the health problem?

Recovered or Resolved

#### Affected Person

Affected Person Identifier Code

HH

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Male

Race (Select all that apply) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the

problem occurred

<blank>

Select Unit of Age

<blank>

Please list any known preexisting health problems for the affected person

existing health problems for Patient has history of migraines, nicotine addiction, marijuana daily use.

# **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

No prescription medications, no OTC, no vitamins. Uses nicotine and marijuana daily.

# What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping <blank> product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, <blank> electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine

Was the e-liquid dripped on to the atomizer or heating element?

<blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Uses JUUL with marijuana + nicotine.

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

Yes

Describe what substances are being mixed with the tobacco product

Marijuana. Urine tox was consistent with just marijuana and nicotine.

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

2

Select Unit of Measure

Year(s)

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

<blank>

Select Unit of Measure

<blank>

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

<blank>

Did this same or similar problem happen again after repeat use of the tobacco product?

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

#### **Other Tobacco Products**

Tobacco Product Type Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

<blank>

#### Other Tobacco Products

Tobacco Product Type Roll-your-own cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

<blank>

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

#### **Attached Files**

None



#### REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-08

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# **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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	 <blank></blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	   
Job Title	   
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Mother

# **Problem Summary**

**Problem Start Date** 03/09/2019

**Problem End Date** 03/28/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Our son had 2 passing out episodes. One immediately followed a vaping occasion and the other may have been tied to vaping. We only witnessed 1 of the passing out episodes and it appeared as if it was a mild seizure (pale face, pale lips, eyes rolled back before passing out). I saw a report on The Today Show and wanted to report this. We are trying everything to keep our son from vaping, but he is too easily getting access to vape devices and vape "juice" through friends or siblings of friends. Please partner with the public schools to provide more education.

Do any of these apply to the health problem? (Select one None of the above or more)

Treatment Received (select all that apply)

Self-Treated

Please describe treatment the person received. including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

My mother-in-law was here at the time and she is a nurse. We had our son lay down, got a cool compress, and later gave him water.

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

Select Unit of Time

minute(s)

What is the current status of the health problem?

Unknown

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender Male

Race (Select all that apply) White

Ethnicity <blank>

Birth date of the person who experienced the problem

Age of the person when the problem occurred

14

Select Unit of Age

year(s)

Please list any known preexisting health problems for no known

the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

# What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the eliquid, e-juice or vape juice

Purchased for use in a capsule, tank or refillable cartridge

for your electronic cigarette, electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

unknown

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

Product was discarded

How was this product acquired?

From a Friend

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is Some Days this tobacco product used?

Are other substances being <blank> mixed in with the tobacco product when used?

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of

tobacco product?

Select Unit of Measure Month(s)

How soon after the tobacco product was last used did

the problem occur?

5

Select Unit of Measure Month(s) How long has the person been using this particular brand or label?

Select Unit of Measure

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Unknown

Did this same or similar problem happen again after Yes repeat use of the tobacco product?

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

#### **Tobacco Product Parts**

#### **Other Products Used**

## **Other Tobacco Products**

#### **Additional Information**

### **Attached Files**

None

CTU No.: FDA-CDER-CTU-2019-(6) (6) | Department: CTP | RCT No.: RCT-(5) (6) | CTU Triage Date: 07-04-2019 | Total Pages:

All dates displayed in the report are in EST(GMT-05:00) time zone

Test Result

Basic Det	ails	We shall be seen to the				
Company	Unit	CDER-CTU	Originating Account	FAERS		
Source Me	dium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority		Routine				
Override A	uto Calculation Rule	No				
FDA Rece	ived Date	05-Apr-2019	CTU Received Date	05-Apr-2019		
CTU Triag	e Date		CTU Data Entry Date			
Report Type		Spontaneous	Report Classification	Drug		
Assign To		User				
User/Grou	p					
Forward to	Department	DODER (CDER OS	SE-RSS-CTU@fda.hhs.gov) (E2B)			
Case Prior	itv	Direct	bE-Noo-CTO@ida.nins.gov) (E2B)			
	-7	APACE .				
Contact						
Case	First Name	Last Name	Email Address	Phone		
Reporter	(b) (6)	(b) (6)	(b) (6)	(6) (6)		
$\square$		(6/10/	(5) (5)	(0) (0)		
Continu A	- About the Problem					
		Noticed a problem with the quality of the product  Had problems after switching from one product maker to another maker				
Date th	e problem occurred	15-Jul-2013				
Serious		Yes				
	of the following happen? all that apply)	happen?  Hospitalization – admitted or stayed longer  Required help to prevent permanent harm  Disability or health problem  Birth defect  Life-threatening  Death  Other serious/important medical incident(Please Describe Below)				
	erious/important medical t(Please Describe Below)					
4.Tell us v any additi	what happened and how onal documents if nece	w it happened (Includ	le as many details as possible F	DA may reach out to you for		
Possibl was wit	e seizure do to ECIG Had h me I started to having se	recently started using E izure luckily partner was chiatric problems. I did r	CIG. Had no history of seizure. On fr s there with me to take over the vehic eport to my Dr. Webber. I have had p	cle. I also experienced lots of out		
Relevant	Test/Laboratory Data			1 of 1		
Test No			Test Date	1011		

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Test Unit

	Low Test Range		High Test Range		
	More Information Available?				
Α	dditional Comments				
	ECIG and Vapor. No stopped vap	ing a long time ago.			
S	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
S	ection C - About the Products				1 of 1
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Cosmetic, Dietary Supplement	ent or Food/Medicinal Fo	od	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Ecig			
	Name of the company that makes (or compounds) the product	Ecig			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?				
	Did the problem return if the person started taking or using the product again?				
D	rug Therapy				1 of 1
	Expiration date				T 1 T 2 1   [1
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product				

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Receipt No: RCT-(b) (6) \_\_\_\_\_ FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019(b) (6) | Department: CTP | RCT No.: RCT (b) (6) | CTU Triage Date: 07-04-2019 | Total Pages: 5

H	Date the person stopped taking or using the product		
	Give best estimate of duration		
П	Is therapy still on-going?	Yes	
W	hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		F.
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		Ī
Oi	ther identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		П
	UDDI Number		
	Expiration date	The state of the s	
	Was someone operating the medical device when the problem occurred?		
Fo	or implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
D	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	no Had the Problem	
	Person's Initials	(b) (r)	
	Gender	Male	
	Age (specify unit of time for age)	37 Year(s)	
	Date of Birth		
	Weight	93.15 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

tion F - About the Perso	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
_ast name	(b) (6)	
Middle Name	1 22	
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(010)	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
-ax		
Reporter Organization		

CTU No.: FDA-CDER-CTU-2019-101 (6) | Department: CTP | RCT No.: RCT-10 (6) | CTU Triage Date: 07-04-2019 | Total Pages: 5

Department		
Reporter Speciality		
Today's date	05-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		Ī
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 05-Apr-2019 20:45:32 Page 5 of 5



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-08

FDA ICSR ID (b) (6)

Report Key for Followup (b) (6)

# Proxy Report Information (not applicable if this is not a proxy report)

## 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

Both (health problem that is also associated with a product problem or

submitting?

defect)

Did you report this problem somewhere else (outside No SRP)?

# Contact Information - Sender

Organization Name	   
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	 blank>
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	       
Street Address Line 2	        
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	My teenage son

## **Problem Summary**

Product Problem Type (select all that apply)

Other

Describe the other product problem

<blank>

In what setting(s) did this problem occur? (select all that apply)

One person using one or more product(s), Bus/subway/train

**Problem Start Date** 

08/15/2018

Problem End Date

<blank>

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

My son started experiencing seizures after I found out he was experimenting with Juuls, vaping and cannabis oil as well.

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

Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

<blank>

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

## Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender Male

Race (Select all that apply) White

Hispanic or Latino

Birth date of the person who experienced the problem

Ethnicity

Age of the person when the problem occurred

15

Select Unit of Age

year(s)

Please list any known preexisting health problems for Peanut and Tree Nut allergy the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Tonic-clonic seizures

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping <blank> product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, <blank> electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine

Was the e-liquid dripped on to the atomizer or heating element?

Yes

Full Tobacco Product Name. including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Unknown

How was this product acquired?

From a Friend

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is <blank> this tobacco product used?

Are other substances being mixed in with the tobacco product when used?

Did the problem occur with first time use of the tobacco <blank>

product?

How long has the person been using this type of

tobacco product? Select Unit of Measure

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

Select Unit of Measure

Unknown

<blank>

<blank>

<blank>

<blank>

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products No (either currently or in the past)?

#### Other Tobacco Products

#### **Additional Information**

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

My son was a healthy boy before I found out that he was experimenting with e-cigarettes. He now has been diagnosed with Epilepsy and is on medication. I understand that parents are also part of this problem

problem. Attachments may be added on the next page.

where they are purchasing these gadgets for their kids enabling their teenage sons and daughters. Which is extremely careless on their part. We need to do more to stop this epidemic and to stop kids from getting sick and addicted to nicotine and cannabis.

## **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-08

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## Report Identifying Information

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Voluntary

Regulatory Status

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

#### Contact Information - Sender

**Organization Name** <blank> **Confirm Email** (b) (6) **First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> Phone Email (If prefilled, changing this email address will not change your Login email ID) **United States** Country Street Address Line 1 Street Address Line 2 <blank> City/Town State ZIP/Postal Code **Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Concerned citizen apply) Are you the person who experienced health No problems associated with a tobacco product? Describe your relationship to the person who Father of person who experineced the problem

## **Problem Summary**

experienced the health

problem

**Problem Start Date** 

01/17/2019

**Problem End Date** 

01/17/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

My daughter was driving her car and took a hit of an e-cigarette. Within 15 seconds she started to feel odd. She pulled over but went into a grand maul seizure. That seizure caused her to step on the gas. She crashed into the car in front of her and into a wall. this was the 3rd seizure she had immediately after having a e-cigarette. Her doctor said that that she must have epilepsy which is why she thought it was ok to vape again. But, after changing doctors and tests, she has no signs of epilepsy. Her Doctor believes, as well as all of us, that she has seizures due to the high levels of nicotine in the e cigarettes. She has not had a seizure again.

Do any of these apply to the health problem? (Select one None of the above or more)

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received. including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

The doctor did the test to see if she had any signs of epilepsy. The test came up negative.

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

Select Unit of Time

minute(s)

What is the current status of the health problem?

Recovered or Resolved

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

Female Gender

Pregnant No

Race (Select all that apply) <blank>

**Ethnicity** Unknown

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the

problem occurred

16

Select Unit of Age year(s)

Please list any known preexisting health problems for No pre-existing health problems the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

na

## What are the main symptoms or health problems?

Term describing the health problem

Prolonged seizure

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto.

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

for your electronic cigarette, Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Tobacco, Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Phix and Sourin Drop

When did the person purchase this product?

01/17/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Retailer/Distributor has the product

How was this product acquired?

From a Friend

Do you know where the product was purchased?

No

Manufacturer Name

Other

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) Phix and Sourin Drop

Country United States

Phone <br/> <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <br/> <br/>

ZIP/Postal Code <br/>
<b

Web Address <br/> <blank>

Email Address <br/> <blank>

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Rarely

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco Yes product?

How long has the person been using this type of tobacco product?

<blank>

Select Unit of Measure

<blank>

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

15

Select Unit of Measure

Second(s)

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

#### Additional Information

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. She had vaped before with no issue, but two times she used a brand called PHIX she went into Seizure. She stopped for a year and her doctor assured her that the vape did not cause the issue. She also was put on epilepsy medicine. SHe vaped again and nothing happened, but then she vaped a few days later a brand called Sourin Drop and within 15 seconds, just like with the PHIX, she went into a grand maul seizure.

#### **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-08

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

## 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

#### Contact Information - Sender

Organization Name N/A

Confirm Email (b) (6)

First Name (b) (6)

Last Name (b) (6

Did you report the problem to the manufacturer? <br/>
<bloom>

Job Title <br/>
<b

Phone (b) (6)

Email (If prefilled, changing this email address will not change your Login email ID)

(b) (6)

**Country** United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that Consumer, Concerned citizen

apply)

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

Yes

04/08/2019

**Problem Summary** 

**Problem End Date** 

Problem Start Date 02/01/2018

Please describe the health I began vaping a about a year ago, and one day after I had been vaping problem or product problem. on and off for a couple of months I passed out and hit my head on

The Attachments page will accept uploads of any records, pictures, or other information.

concrete giving me a concussion. Since then I have continued to vape, but about once a week I will experience a seizure when vaping. I get light headed, lose control of my body, start drooling and black out for any where between a few seconds and a minute (I am not sure how much time has passed when it happens). The problem happens after using a Sourin Air with 60 mg nictotine salt juice.

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

None of the above

Treatment Received (select all that apply)

None

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

Select Unit of Time

month(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

**Ethnicity** 

1

Gender Male

Race (Select all that apply) White

Not Hispanic or Latino

Birth date of the person who experienced the problem

b) (6)

Age of the person when the problem occurred

18

Select Unit of Age

year(s)

Please list any known preexisting health problems for no pre existing problems the affected person

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

none

## What are the main symptoms or health problems?

Term describing the health problem

Partial seizures, simple

#### **Tobacco Products**

Tobacco Product Type

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Mixed in a shop or on-line per request or 'to order"

Describe the e-liquid mix

60 mg 30 ml nicotine salt juice

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Other

Describe other e-liquid flavor(s)

Mango

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Sourin Air

When did the person purchase this product?

03/01/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product acquired?

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location Name** Mushroom

Country **United States** 

Phone <blank>

Street Address Line 1 1037 Broadway St

Street Address Line 2 <blank>

City/Town New Orleans

State Louisiana

ZIP/Postal Code 70118

Web Address <blank>

**Email Address** <blank>

### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

1

Select Unit of Measure

Year(s)

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

2

Select Unit of Measure

Month(s)

How long has the person been using this particular brand or label?

1

Select Unit of Measure

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

<blank>

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products No (either currently or in the past)?

## **Other Tobacco Products**

## Additional Information

Please describe anything else you think the FDA should know about this <br/>problem. Attachments may be added on the next page.

#### **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-08

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## Report Identifying Information

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	        
Confirm Email	(b) (6)
First Name	(b) (8)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	   
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	MOTHER

# **Problem Summary**

Problem Start Date 09/06/2018

Problem End Date 04/08/2019

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

Focal, Temporal and Partial Complex seizures

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

Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

He is now taking antiseizure medicaitons for the first time in 5 years.

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

month(s)

What is the current status of

Select Unit of Time

the health problem?

Not Recovered or Unresolved

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

How many nonusers were

<blank>

affected?

Gender Male

Race (Select all that apply) White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

20

Select Unit of Age

year(s)

Please list any known preexisting health problems for History of seizures

the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Juul Vape

## What are the main symptoms or health problems?

Term describing the health

problem

Partial seizures, complex

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

Electronic cigar or e-cigar

Select all that apply to the electronic cigarette,

Rechargeable product

electronic nicotine or vaping product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

<blank>

Was the e-liquid dripped on to the atomizer or heating element?

<blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

<blank>

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

## **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is Every Day this tobacco product used?

Are other substances being No mixed in with the tobacco

product when used?

Did the problem occur with first time use of the tobacco No

product?

How long has the person been using this type of tobacco product?

Select Unit of Measure

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

Select Unit of Measure

<blank>

Year(s)

<blank>

How long has the person been using this particular brand or label?

1

Select Unit of Measure

Year(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

## **Other Tobacco Products**

**Tobacco Product Type** 

Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

No

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

Just wondering if the use of the Juul is connected to him starting to have seizures again.

# **Attached Files**

None



## REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-09

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside Yes SRP)?

Describe who the problem was reported to

my general physician and doctors at the hospital

## Contact Information - Sender

Organization Name

Confirm Email

First Name

Last Name

Did you report the problem to the manufacturer?

Job Title

Phone

Email (If prefilled, changing this email address will not change your Login email ID)

Country United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that

apply)

Consumer

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

Yes

## **Problem Summary**

Problem Start Date <br/>
Problem End Date <br/>

Please describe the health experienced syncope or seizure while using tobacco vapor product that problem or product problem. was the only substance being used during the incident. blacked out and

The Attachments page will accept uploads of any records, pictures, or other information.

fell to the floor and started convulsing. first time that's ever happened to me before, anything like that, it started off like a nicotine buzz but turned into anxiety almost, then black out.

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

Life threatening

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

family care doctor took blood that came back normal. [also got an MRI of the brain that came back normal, and a heart ultrasound that came back normal although I had fluid in my lungs (probably due to the vape) and a holter monitor to monitor heart activity.

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)

What is the current status of the health problem?

Not Recovered or Unresolved

## Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

1

affected?

. . . . . .

Gender

Male

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the

problem occurred

18

Select Unit of Age

year(s)

Please list any known preexisting health problems for anxiety

the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Partial seizures, complex

## **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the eliquid, e-juice or vape juice electronic nicotine or vaping product

for your electronic cigarette, Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Propylene Glycol, Water

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit, Candy or Chocolate

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

sourin air vape with solace e liquid

When did the person purchase this product?

03/15/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

638317258076

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

solace e liquid. made in Los Angeles California. strawberry hard candy flavor

What is the country of manufacture of the tobacco product?

United States

Where is the tobacco product now?

Product was discarded

How was this product acquired?

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

Other

## **Tobacco Product Packaging and Portions**

## Manufacturer Investigation Information

#### **Tobacco Product Purchase Location**

Purchase Location Name wild Bill's smoke shop

Country United States

Phone <black>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town roseville

State Michigan

ZIP/Postal Code 48066

Web Address <br/>

Email Address <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

## **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) solace

Country United States

Phone <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town Los Angeles

State California

ZIP/Postal Code <br/>
<b

Web Address <br/> <br/>

Email Address <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

<blank>

Did the problem occur with first time use of the tobacco product?

No

How long has the person been using this type of tobacco product?

1

Select Unit of Measure

Year(s)

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

5

1

Select Unit of Measure

Minute(s)

How long has the person been using this particular brand or label?

Select Unit of Measure

Weeks(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

## **Tobacco Product Parts**

## **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

## **Other Tobacco Products**

## **Additional Information**

Please describe anything
else you think the FDA
should know about this
problem. Attachments may
be added on the next page.

#### **Attached Files**

None



## REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-09

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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



Regulatory Status Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

## Contact Information - Sender

Organization Name (b) (6)

Confirm Email (b) (6)

First Name (b) (6

Last Name (b) (6)

Job Title (b) (6)

Phone (b) (6)

Email (If prefilled, changing this email address will not change your Login email ID)

Login email ID)

Country United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that

Citizen Type (select all tha apply)

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

Consumer, Concerned citizen

<blank>

## **Problem Summary**

Problem Start Date 12/21/2018

Problem End Date 12/21/2018

Please describe the health problem or product problem. I had a seizure and suspected it was from using my Juul.

The Attachments page will accept uploads of any records, pictures, or other information.

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

None of the above

Treatment Received (select all that apply)

Self-Treated

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

<blank>

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

Select Unit of Time minute(s)

What is the current status of the health problem?

Recovered or Resolved

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Male

Race (Select all that apply)

White

**Ethnicity** 

Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

Select Unit of Age

year(s)

Please list any known preexisting health problems for <blank> the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

## **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

Purchased in a non-refillable disposable cartridge

electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Glycerin, Propylene Glycol

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Mango flavored Juul

When did the person purchase this product?

12/21/1993

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

<blank>

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Some Days

Are other substances being mixed in with the tobacco product when used?

Yes

Describe what substances are being mixed with the tobacco product

Alcohol

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

Select Unit of Measure

Year(s)

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

10

Select Unit of Measure

Minute(s)

How long has the person been using this particular brand or label?

1

Select Unit of Measure

Year(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

No

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

## **Other Tobacco Products**

## Additional Information

Please describe anything else you think the FDA should know about this My nickname after the seizure to my friends was (b) (6) for a short period because due to no prior history of seizures it was assumed by the group that this product was the cause.

problem. Attachments may be added on the next page.

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-09

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

Create a name to help you find this report in the future

(b)(6)

(max length: 50 characters)

**Regulatory Status** Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

## **Contact Information - Sender**

**Organization Name** <blank> **Confirm Email** <blank> **First Name** <blank>

**Last Name** <blank>

Did you report the problem to the manufacturer?

No

Job Title <blank> Phone

Email (If prefilled, changing this email address will not change your Login email ID)

<blank>

<blank>

Country <blank>

Street Address Line 1 <blank> Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

**Sender Category** Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that

apply)

<blank>

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

No

Describe your relationship to the person who experienced the health

<blank>

problem

# **Problem Summary**

Problem Start Date <br/>

Problem End Date <br/>
<

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Individual had vaped a nicotine product. He then had a very emotionally upsetting incident during which he became very angry. About 2hours later he suffered an extremely serious seizure, loss of time, loss of memory, incoherent thoughts and speech, poor muscle control. The seizure and after effects lasted for 18 hours.

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

Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Anti seizure medication, mri, eeg

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

month(s)

What is the current status of the health problem?

Select Unit of Time

Not Recovered or Unresolved

## Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

17

Gender

Male

Race (Select all that apply)

White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

19

Select Unit of Age

year(s)

Please list any known preexisting health problems for None the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

## What are the main symptoms or health problems?

Term describing the health problem

Other

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** 

vaporizer

Select all that apply to Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Uses a tank or tank system, Puff/flow the electronic cigarette, electronic nicotine or vaping activated

product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

for your electronic cigarette, Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Candy or Chocolate

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Soren pod

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

## **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is Every Day this tobacco product used?

Are other substances being No mixed in with the tobacco

product when used?

Did the problem occur with first time use of the tobacco No

product?

How long has the person been using this type of tobacco product?

Select Unit of Measure

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

Select Unit of Measure

Year(s)

20

Minute(s)

How long has the person been using this particular brand or label?

1

Select Unit of Measure

Year(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

No

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

## **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

## **Other Tobacco Products**

**Tobacco Product Type** 

Cigarette

**Tobacco Product Subtype** 

<blank>

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

## **Attached Files**

None

CTU No.: FDA-CDER-CTU-2019 (6) | Department: CTP | RCT No.: RCT (b) (6) | CTU Triage Date: 09-04-2019 | Total Pages: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

sic Det		CDER CTU	Originating Associat	EAEDS	
ompany		CDER-CTU	Originating Account	FAERS	
ource Me	ealum	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority		Routine			
540470 004 277	Auto Calculation Rule	No		Turning	
W-10 10 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	ived Date	08-Apr-2019	CTU Received Date	08-Apr-2019	
CTU Triag	4/2 4/4/2		CTU Data Entry Date	31.7	
Report Ty		Spontaneous	Report Classification	Drug	
Assign To		User			
Jser/Grou	,				
Forward to	Department	CDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Prio	rity	Direct			
ontact	Contract of the Contract of th	A STATE OF	10000000	10000	
Case Reporter	First Name	Last Name	Email Address	Phone	
Z	(b) (6)	(b) (6)			
Date th	ne problem occurred	Had problems after swit	ching from one product maker to another mak	er	
Seriou	3	No			
Did any of the following happen? (Check all that apply)		Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)			
ny additi Reocci	onal documents if nece urring issue has occurred w	w it happened (Includ ssary) vith me when using juul.	le as many details as possible F  I have had a tremor problem worser d affect other areas of my body.	A	
Relevant	Test/Laboratory Data		47.7	1 of 1	
Test N	ame	MRI	Test Date	14-Mar-2019	

levant Test/Laboratory Data	· .		1 of 1
Test Name	MRI	Test Date	14-Mar-2019
Test Result	Normal functions in brain a nd spine	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

CTU No.: FDA-CDER-CTU-2019 (6) Department: CTP | RCT No.: RCT-(9) (6) | CTU Triage Date: 09-04-2019 | Total Pages: 5

ĮΑ	dditional Comments				
Se	ection B - Product Availability	April 1			
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ection C - About the Products				1 of 1
	Suspect	Yes			2372
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Drug			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	luuk			
	Name of the company that makes (or compounds) the product	Juul			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				177.4
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?	Yes			
Di	rug Therapy				1 of 1
1	Expiration date				
	Lot number				
	Dosage Form			9	
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Respiratory (inhalation)	If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Give best estimate of duration	6 Month			

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Receipt No: RCT-(b) (6)

CTU No.: FDA-CDER-CTU-2019-(5) (6) | Department: CTP | RCT No.: RCT-(b) (6) | CTU Triage Date: 09-04-2019 | Total Pages: 5

Is therapy still on-going?		
Why was the person using the pro	oduct? (such as what condition was it supposed to treat) 1 of 1	
Recreational		
Returned to Manufacturer On		
Section D - About the Medical De	vice	
Name of medical device		Т
Name of the company that makes the medical device		Ī
Other identifying information (The locate them)	model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
Model Number		
Catalog Number		T
Lot Number		ī
Serial Number		ī
UDDI Number		Ī
Expiration date		Ī
Was someone operating the medical device when the problem occurred?		
For implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
Date the implant was put in	Date the implant was taken out (If relevant)	
Section E - About the Person Wh	o Had the Problem	
Person's Initials	(C) (C)	T
Gender	Male	+
Age (specify unit of time for age)	18 Year(s)	T
Date of Birth		Т
Weight	56.25 kg	Ħ
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

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	Dépression/anxiety	
PI	ease list all allergies (such as to drugs, foods, pollen or others)	
Li	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Li	st all current prescription medications and medical devices being used.	
	Zoloft	
Li	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	Vitamin D	
0	ection F - About the Person Filling Out This Form	

Primary?	Filling Out This Form Yes	
Reporter is Patient?		
Fitle		
ast name	(b) (6)	
vliddle Name		
First name	(b) (6)	
Number/Street		
City		
State/Province	=-	
Country	USA	
ZIP or Postal code	1, 2	
Telephone number		
Email address		
ax		
Reporter Organization	-: 1	
Department		
Reporter Speciality		

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FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (b) | Department: CTP | RCT No.; RCT (b) (6) | CTU Triage Date: 09-04-2019 | Total Pages;
5

Today's date	08-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM 08-Apr-2019 20:45:28 Page 5 of 5 Generated on:

CTU No.: FDA-CDER-CTU-2019-(0) (6) | Department: CTP | RCT No.: RCT(b) (6) | CTU Triage Date: 09-04-2019 | Total Pages:

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	A		10.00			
Company Unit	CDER-CTU	Originating Account	FAERS			
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority	Routine	1				
Override Auto Calculation Rule	No					
FDA Received Date	09-Apr-2019	CTU Received Date	09-Apr-2019			
CTU Triage Date		CTU Data Entry Date				
Report Type	Spontaneous	Report Classification	Drug			
Assign To	User	L.				
User/Group						
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)				
Case Priority	Direct					

Contact	Contact						
Case Reporter	First Name	Last Name	Email Address	Phone			
	(b) (6)	(b) (6)	(b) (6)	(b) (6)			

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)  Used a product incorrectly which could have or led to a problem  Noticed a problem with the quality of the product  Had problems after switching from one product maker to another maker	
Date the problem occurred	30-Mar-2019	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)	2 seizure incidents with hos	

# 4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Started to use Juul in November 2018. In December I suffered the first seizure event in my life and was hospitilized. At that time, I did not associate the incident with the use of Juul. In March 2019, however, I suffered a second seizure incident. Again I ended up being hospitilized. During hospitalization I was submitted to lots of exams, which determined that I have nothing in my brain that would justify seizure events and that therefore, these incidents would likely be linked to or resulting from poisoning nicotine.

Relevant Test/Laborato	ry Data	6	1 of 1
Test Name	BRAIN MAGNETIC RESS ONANCE	Test Date	31-Mar-2019
Test Result	Nothing was identified	Test Unit	PERCENT

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019-101 (6) | Department: CTP | RCT No.: RCT-19) (6) | CTU Triage Date: 09-04-2019 | Total Pages: 5

	Low Test Range	High Test Ra	ange	
	More Information Available?		1 1	
A	dditional Comments			
	No abnormal results			
S	ection B - Product Availability			
	Do you still have the product in	Yes		
	case we need to evaluate it?  Do you have a picture of the product? (check yes if you are including a picture)	No		
S	ection C - About the Products		1 of 1	
	Suspect	Yes		
	Primary?	Yes	1	Ħ
	Туре	Drug/Biologic		Ī
	This report is about	Cosmetic, Dietary Supplement or Food/Me	edicinal Food	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Juul with 5% nicotine juul pods		
	Name of the company that makes (or compounds) the product	Juul		Ī
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Generic Biosimilar	Facility	
	Strength	If Other		1
	NDC number			Ξ
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		I
	Did the problem return if the person started taking or using the product again?	Doesn't Apply		
D	rug Therapy		1 of 1	
	Expiration date			
	Lot number			
	Dosage Form	1-04	· ·	
	Quantity	If Other		1
	Frequency	If Other		
	How was it taken or used	If Other		
	Date the person first started taking or using the product	01-Nov-2018		

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Receipt No: RCT-(b) (6) FDA 3500B Form

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 (b) (6) | Department: CTP | RCT No.: RCT (b) (6) | CTU Triage Date: 09-04-2019 | Total Pages: 5

	Date the person stopped taking or using the product	30-Mar-2019	
	Give best estimate of duration		
Ħ	Is therapy still on-going?		
W	hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Started to use Juul in attemp to qu	uit smoking	
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
17	Name of medical device		
	Name of the company that makes the medical device		
Ot	ther identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fc	r implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
D	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	no Had the Problem	
	Person's Initials	10 10	
	Gender	Male	
	Age (specify unit of time for age)		
	Date of Birth	(b) (6)	
	Weight	67 kg	
П	Ethnicity (Choose only one)	Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White	

Generated by: SYSTEM 09-Apr-2019 06:45:29 Page 3 of 5 Generated on:

Re	ceipt No: RCT <mark>(b) (6)</mark>			(D-1)-(D)		A 3500B Form
	CTU No.: FDA-CDER-CTU-2019(6) (6)	Department:	CIPIRCINO.:	KC1-(D) (D)	C10 Triage Date: 09-04-201	9   Total Pages
_						

t known medical conditio	ons (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
No medical conditions		
and list all allergies (aug	ch as to drugs, foods, pollen or others)	
Allergic to peniciline only	arias to drugs, toods, polien or others)	
, morgro to pornomino omy		
any other important info	ormation about the person (such as smoking, pregnancy, alcohol use, etc.)	
N/a		
all current prescription	medications and medical devices being used.	
Lyrica to diminish risks of a		
all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being	used.
		of 1
Primary?	Yes	
Reporter is Patient?		
Title	The results	
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province		
Country	(b) (6)	
ZIP or Postal code	(b) (6)	
To land formers to see the sec		
Telephone number	(b) (6)	

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Fax

Reporter Organization

CTU No.; FDA-CDER-CTU-2019 (6) | Department: CTP | RCT No.; RCT (b) (6) | CTU Triage Date: 09-04-2019 | Total Pages; 5

Department		
Reporter Speciality		
Today's date	09-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 (5) | Department: CTP | RCT No.: RCT(D) (6) | CTU Triage Date: 03-04-2019 | Total Pages: 5

asic Details					
company Unit		CDER-CTU	Originating Account	FAERS	
Source Mediu	m	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority		Routine	j.	+	
Override Auto	Calculation Rule	No			
DA Received	l Date	03-Apr-2019	CTU Received Date	03-Apr-2019	
CTU Triage Da	ate		CTU Data Entry Date		
Report Type		Spontaneous	Report Classification	Drug	
Assign To		User			
Jser/Group					
orward to De	partment	CDER (CDER-O	SE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority		Direct	<u> </u>		
ontact		1	10000	190	
Reporter	First Name	Last Name	Email Address	Phone	
2	b) (6)	(b) (6)			
ection A - A	bout the Problem	200			
Date the pr	roblem occurred	The state of the s	the quality of the product tching from one product maker to another make	er	
Serious		Yes			
Did any of (Check all	the following happen? that apply)	Hospitalization - admitted Required help to prever Disability or health prob Birth defect Life-threatening Death	nt permanent harm elem		
Other serio	ous/important medical	✓ Other serious/important medical incident(Please Describe Below)     Seizures			
incident(Pl	ease Describe Below)	Carriera .			
Tell us wha	it happened and how Il documents if nece	v it happened (Includ	de as many details as possible f	DA may reach out to you t	
When I was	s vaping i started havin	g seizures. It started as n mechanical mods and	i just one but it has been 2 years now d had 1.5milligram nicotine. Also whil		
elevant Tes	t/Laboratory Data			1 of 1	
				+ *1 1	

Relevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019-101 (6) | Department: CTP | RCT No.: RCT (b) (6) | CTU Triage Date: 03-04-2019 | Total Pages: 5

	More Information Available?		
Αc	ditional Comments		
	It has been 4 years since I quit va	ping. I still have irregular heart beats and most recent seizure was about two months ago.	
Se	ction B - Product Availability		
	Do you still have the product in case we need to evaluate it?	Yes	
	Do you have a picture of the product? (check yes if you are including a picture)	No	
Se	ction C - About the Products	1 of 1	
	Suspect	Yes	
П	Primary?	Yes	
	Туре	Drug/Biologic	
	This report is about	Cosmetic, Dietary Supplement or Food/Medicinal Food	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	It was a bulk Eliquid	
	Name of the company that makes (or compounds) the product		
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar	
	Strength	If Other	
Ħ	NDC number		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No	
	Did the problem return if the person started taking or using the product again?	Yes	
Dr	ug Therapy	1 of 1	
1	Expiration date		
	Lot number		
	Dosage Form		
1-1	Quantity	If Other	
įπ	Frequency	If Other	
	How was it taken or used	If Other	
	Date the person first started taking or using the product  Date the person stopped taking or using the product		

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Receipt No: RCT-(b) (6) FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 (6) | Department: CTP | RCT No.: RCT-(b) (6) CTU Triage Date: 03-04-2019 | Total Pages:

Give best estimate of duration 1 Year Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 Suppose to help quit cigarettes Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number **UDDI Number** Expiration date Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If Date the implant was put in relevant) Section E - About the Person Who Had the Problem Person's Initials Unspecified Gender Male 23 Year(s) Age (specify unit of time for age) Date of Birth Weight 74.25 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American

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

Generated by: SYSTEM Generated on: 03-Apr-2019 17:15:41 Page 3 of 5

Past heart issue known as	SVT	
Please list all allergies (suc	ch as to drugs, foods, pollen or others)	
None	** *** *** **** <b>*</b> ** *** *** *** *** **	T
ist any other important info	ormation about the person (such as smoking, pregnancy, alcohol use, etc.)	
ist all current prescription	medications and medical devices being used.	
ist all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being used	
		-  -
Section F - About the Perso		
Primary?	on Filling Out This Form 1 of 1	
	on Filling Out This Form 1 of 1  Yes	
Reporter is Patient?		
Reporter is Patient?  Title		
The second secon	Yes	
Title		
Title Last name	Yes	
Title  Last name  Middle Name	Yes (b) (6)	
Title Last name Middle Name First name	Yes (b) (6)	
Title  Last name  Middle Name  First name  Number/Street	Yes (b) (6)	
Title  Last name  Middle Name  First name  Number/Street  City  State/Province	Yes  (b) (6)  (b) (6)	
Title  Last name  Middle Name  First name  Number/Street  City  State/Province  Country	Yes (b) (6) (b) (6)	
Title  Last name  Middle Name  First name  Number/Street  City  State/Province  Country  ZIP or Postal code	Yes  (b) (6)  (b) (6)	
Title  Last name  Middle Name  First name  Number/Street  City  State/Province  Country	Yes  (b) (6)  (b) (6)	

Generated by: SYSTEM Generated on: 03-Apr-2019 17:15:41 Page 4 of 5

Reporter Organization

Reporter Speciality

Department

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (0) | Department: CTP | RCT No.; RCT-(0) (6) | CTU Triage Date: 03-04-2019 | Total Pages;
5

Today's date	03-Apr-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

Generated by: SYSTEM 03-Apr-2019 17:15:41 Page 5 of 5 Generated on:

All dates displayed in the report are in EST(GMT-05:00) time zone

Low Test Range

ompany Unit	C	DER-CTU	Originating Account	FAERS
ource Medium	N	/WO (Drug)	Source Form Type	E2B XML 3500B
iority	F	Routine		
verride Auto Calculat	tion Rule N	lo		
DA Received Date	0	3-Apr-2019	CTU Received Date	03-Apr-2019
TU Triage Date			CTU Data Entry Date	
eport Type	S	Spontaneous	Report Classification	Drug
ssign To	L	Jser		
ser/Group				
orward to Department	t	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
ase Priority		Direct	3-7,(,	
ontact ase First Nam	ne	Last Name	Email Address	Phone
eporter (b) (6)		(b) (6)	(b) (6)	
ection A - About the				
		-	n the quality of the product nitching from one product maker to another maker	er
Data the weekless a		Had problems after sw		eer
Date the problem of Serious	ccurred 2	Had problems after sw 3-Oct-2013		ser
Date the problem of Serious  Did any of the follow	ccurred 2	Had problems after sw 3-Oct-2013 'es	itching from one product maker to another mak	eer
Serious	ving happen?	Had problems after sw 3-Oct-2013  es  Hospitalization - admitt Required help to preve Disability or health problems Birth defect Life-threatening Death	ted or stayed longer ent permanent harm	eer
Serious  Did any of the follow	ving happen? [ [y) [ [c]	Had problems after sw 3-Oct-2013  es  Hospitalization - admitt Required help to preve Disability or health problems Birth defect Life-threatening Death	itching from one product maker to another maker to anothe	eer
Serious  Did any of the follow (Check all that apply)  Other serious/importincident(Please Design	wing happen? [ y)  Itant medical scribe Below)  ened and how i	Had problems after sw 3-Oct-2013  es  Hospitalization - admitt Required help to preve Disability or health prof Birth defect Life-threatening Death Other serious/importances  t happened (Inclu	ted or stayed longer ent permanent harm	
Other serious/imporincident(Please Designational documents)  After seeing the infostarted having seizu been found. I started	wing happen?  (y)  Itant medical scribe Below)	Had problems after sw 3-Oct-2013  Tes  Hospitalization - admitt Required help to preve Disability or health prof Birth defect Life-threatening Death Other serious/important Seizures  t happened (Includary) d today about a possit of nowhere and have tes approximately 2	ted or stayed longer ent permanent harm blem	FDA may reach out to you fo s I thought I should report it. I lead many tests and no cause has a heavy smoker at the time but
Other serious/imporincident(Please Designational documents)  After seeing the infostarted having seizu been found. I started	wing happen?  wing happen?  y)  rtant medical scribe Below)  ened and how inents if necessormation released ures suddenly out of using e cigaret ange to the liquid	Had problems after sw 3-Oct-2013  Tes  Hospitalization - admitt Required help to preve Disability or health prof Birth defect Life-threatening Death Other serious/important Seizures  t happened (Includary) d today about a possit of nowhere and have tes approximately 2	ted or stayed longer ent permanent harm blem  at medical incident(Please Describe Below)  de as many details as possible I sible link between vaping and seizure we been diagnosed epileptic. I have hweeks prior to them beginning. I was	FDA may reach out to you fo s I thought I should report it. I lead many tests and no cause has a heavy smoker at the time but
Other serious/imporincident(Please Designational documents)  After seeing the information of the serious of the serious of the seeing the information of the started having seizu been found. I started dont know if the characteristic of the serious	wing happen?  wing happen?  y)  rtant medical scribe Below)  ened and how inents if necessormation released ures suddenly out of using e cigaret ange to the liquid	Had problems after sw 3-Oct-2013  Tes  Hospitalization - admitt Required help to preve Disability or health prof Birth defect Life-threatening Death Other serious/important Seizures  t happened (Includary) d today about a possit of nowhere and have tes approximately 2	ted or stayed longer ent permanent harm blem  at medical incident(Please Describe Below)  de as many details as possible I sible link between vaping and seizure we been diagnosed epileptic. I have hweeks prior to them beginning. I was	FDA may reach out to you for s I thought I should report it. I had many tests and no cause has a heavy smoker at the time but tently a vaper at the moment.

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High Test Range

Receipt No: RCT-(b) (6)

CTU No.: FDA-CDER-CTU-2018(b) (6) | Department: CTP | RCT No.: RCT(b) (6) | CTU Triage Date: 04-04-2019 | Total Pages: 5

More Information Available?					
lditional Comments					
ction B - Product Availability					
Do you still have the product in case we need to evaluate it?	Yes				
Do you have a picture of the	No				
product? (check yes if you are					
including a picture)					
ction C - About the Products	S				1 of 1
Suspect	Yes				
Primary?	Yes				
Туре	Drug/Biologic				
This report is about	Cosmetic, Dieta	ry Supplement or	Food/Medicina	l Food	
Name of the product as it	Nicotine				
appears on the box, bottle,	e cigarettes				
or package (Include as many names as you see)	32.40.000	la de la companya de			
Name of the company that					
makes (or compounds) the					
product					
Product Type(check all that	Over-the-Count	ter			
apply)	Compounded b	y a Pharmacy or an O	utsourcing Facility		
	Generic				
	Biosimilar				
Strength		If O	ther		
NDC number					
Did the problem stop after the					
person reduced the dose or					
stopped taking or using the product?					
Did the problem return if the					
person started taking or using the	э				
product again?					1 51
ig Therapy					1 of 1
Expiration date					
Lot number					
Dosage Form		1			
Quantity		If O	ther		
Frequency		If O	ther		
How was it taken or used		If O	ther		
Date the person first started taking or using the product					
Date the person stopped taking or using the product					

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Receipt No: RCT-(b) (6) FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-00 (6) | Department: CTP | RCT No.: RCT-00 (6) | CTU Triage Date: 04-04-2019 | Total Pages:

	Give best estimate of duration		
П	Is therapy still on-going?	Yes	
W	hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		Popt In I
Ot	her identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
100	cate them)		
	Model Number	*	
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
D	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	o Had the Problem	
	Person's Initials	ogues .	
	Gender	Male	
	Age (specify unit of time for age)	44 Year(s)	
	Date of Birth		
	Weight	180 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

Page 3 of 5 Generated by: SYSTEM Generated on: 03-Apr-2019 21:15:30

	Epilepsy		7
PI	ease list all allergies (such	as to drugs, foods, pollen or others)	
Lis	st any other important infor	mation about the person (such as smoking, pregnancy, alcohol use, etc.)	
	E cigarette user		
Lis	***************************************	edications and medical devices being used.	
	Keppra, zonagren, lamictal		
Lis	st all over-the-counter medi	ications and any vitamins, minerals, supplements, and herbal remedies being use	d.
Se	ection F - About the Person	Filling Out This Form 1 of 1	
П	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(n) (e)	
	Country	USA	
	ZIP or Postal code	(b) (6)	
	Telephone number		
	Email address	(b) (6)	-11
	Fax		11121
	Reporter Organization		
	Department		

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Reporter Speciality

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (b) | Department: CTP | RCT No.; RCT (b) (6) | CTU Triage Date: 04-04-2019 | Total Pages;
5

Today's date	03-Apr-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM 03-Apr-2019 21:15:30 Page 5 of 5 Generated on:

CTU No.: FDA-CDER-CTU-2019-(b) (6) Department: CTP | RCT No.: RCT-(b) (6) | CTU Triage Date: 03-04-2019 | Total Pages:

asic Deta	ails	and the same of th				
ompany l	Jnit	CDER-CTU	Originating Account	FAERS		
ource Me	dium	MWO (Drug) Source Form Type		E2B XML 3500B		
riority		Routine				
Override Auto Calculation Rule		No				
DA Recei	ved Date	03-Apr-2019	CTU Received Date	03-Apr-2019		
TU Triage	e Date		CTU Data Entry Date			
eport Typ	e	Spontaneous	Report Classification	Drug		
ssign To		User		h		
ser/Group	<b>5</b>	u e				
orward to	Department	CDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)			
ase Priori	ity	Direct	(1-1-1)			
ntact						
ase	First Name	Last Name	Email Address	Phone		
eporter						
3	(b) (6)	(b) (8)	(b) (6)	(b) (6)		
Alam A	- About the Problem					
Date the	e problem occurred	Had problems after swite 01-Jul-2014	ching from one product maker to another make	er		
Serious		Yes				
(Check	onal documents if nece	wit happened (Includessary)	t permanent harm			
seizures	s prior to that.  Test/Laboratory Data	es and started using va		as shortly after. I had never had		
Test Na	ime		Test Date			
Test Re	esult		Test Unit			

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More Information Available?

CTU No.: FDA-CDER-CTU-2019-101 (6) | Department: CTP | RCT No.: RCT-10) (6) CTU Triage Date: 03-04-2019 | Total Pages: 5

A	dditional Comments				
S	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
S	ection C - About the Products				1 of 1
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Drug			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Vuse Solo			
	Name of the company that makes (or compounds) the product				
	Product Type(check all that apply)	Over-the-Counte	r a Pharmacy or an Outsourcing Facility		
	Strength		If Other		
	NDC number				11
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Yes			
D	rug Therapy				1 of 1
	Expiration date				
	Lot number				
	Dosage Form			9	
	Quantity		If Other		
	Frequency		If Other		111
	How was it taken or used		If Other		
	Date the person first started taking or using the product	01-Jul-2014			
	Date the person stopped taking or using the product	03-Apr-2019			
1	Give best estimate of duration				

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Receipt No: RCT-(b) (6) FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-(6) | Department: CTP | RCT No.: RCT-(6) (6) | CTU Triage Date: 03-04-2019 | Total Pages:

Is therapy still on-going?		
Why was the person using the pro	oduct? (such as what condition was it supposed to treat) 1 of 1	
Returned to Manufacturer On		
Section D - About the Medical De	vice	
Name of medical device		
Name of the company that makes the medical device		
Other identifying information (The locate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
Model Number		
Catalog Number		
Lot Number		
Serial Number		
UDDI Number		
Expiration date		
Was someone operating the medical device when the problem occurred?		
For implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
Date the implant was put in	Date the implant was taken out (If relevant)	
Section E - About the Person Wh	o Had the Problem	
Person's Initials	(b)(S)	
Gender	Female	+
Age (specify unit of time for age)		T
Date of Birth	(b) (6)	Т
Weight	90 kg	Ħ
Ethnicity (Choose only one)	Not Hispanic/Latino	T
Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

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	Seizures		
PI		as to drugs, foods, pollen or others)	
	None		
Lis	st any other important inforn	nation about the person (such as smoking, pregnancy, alcohol use, etc.)	
	7-7-		
Li	st all current prescription me	edications and medical devices being used.	
Н	Keppra		
	7 -		
Li	st all over-the-counter medic	cations and any vitamins, minerals, supplements, and herbal remedies being used.	
194	ection F - About the Person	Filling Out This Form 1 of 1	
0.0	Primary?	Yes	
H	Reporter is Patient?		+=
	Title		+
-	Last name	(b) (6)	+
-	Middle Name		
H			-
	First name	(b) (6)	-
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	Link	
	Country	USA	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	11
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		

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FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (0) | Department: CTP | RCT No.; RCT-(0) (6) | CTU Triage Date: 03-04-2019 | Total Pages;
5

Today's date	03-Apr-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM 03-Apr-2019 19:15:29 Page 5 of 5 Generated on:

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 (5) | Department: CTP | RCT No.: RCT-(5) (5) | CTU Triage Date: 11-04-2019 | Total Pages: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		·
Override Auto Calculation Rule	No		
FDA Received Date	10-Apr-2019	CTU Received Date	10-Apr-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	OSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact	E	The state of the s		
Case Reporter	First Name	Last Name	Email Address	Phone
a a	(b) (6)	(b) (6)	(b) (6)	(b) (6)
ection A	- About the Problem			
	nd of problem was it? all that apply)	Used a product incorrectly was Noticed a problem with the c	effect (including new or worsening sympton hich could have or led to a problem quality of the product g from one product maker to another maker	
Date the	e problem occurred	11-Jan-2019	g	
Serious		Yes		
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important med		
	erious/important medical (Please Describe Below)	Seizures		
Tell us w	hat happened and how mal documents if nece	v it happened (Include a	as many details as possible F	DA may reach out to you for
		cently started to have siezu	ires	

Relevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	

CTU No.: FDA-CDER-CTU-2019-01 (5) | Department: CTP | RCT No.: RCT (b) (6) | CTU Triage Date: 11-04-2019 | Total Pages: 5

	More Information Available?				
Ad	lditional Comments				-
Se	ection B - Product Availability				100
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ection C - About the Products				1 of 1
	Suspect	Yes			
	Primary?	Yes			Til it
	Туре	Drug/Biologic			
	This report is about	Drug			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Ecigs juul blu			
	Name of the company that makes (or compounds) the product	Juul blue			
	Product Type(check all that apply)	Over-the-Counter Compounded by a l	Pharmacy or an Outsourcing F	acility	
	Strength		If Other		
	NDC number			1	
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?	Yes			
Dr	ug Therapy				1 of 1
11	Expiration date				
	Lot number				
	Dosage Form				
1-1	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking				

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	Give best estimate of duration	The state of the s	
	Is therapy still on-going?		H
W	The state of the s	oduct? (such as what condition was it supposed to treat) 1 of 1	h
	Quit smoking		
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Oi	ther identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
3	Catalog Number		
	Lot Number		
i	Serial Number		
	UDDI Number		
1	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
D	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	no Had the Problem	
	Person's Initials	Dkb	
	Gender	Male	
	Age (specify unit of time for age)	30 Year(s)	П
	Date of Birth		Ħ
	Weight	93.15 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

ase list all allergies (such a	to drugs, foods, pollen or others)	
Amoxicillin		
any other important inform	ation about the person (such as smoking, pre	egnancy alcohol use etc.)
Smoking e-cigarettes	ation about the person (such as smoking, pre	sgriancy, alcohol use, etc.)
	lications and medical devices being used.	
Gabbapentin		
all over-the-counter medic	ations and any vitamins, minerals, suppleme	nts, and herbal remedies being used.
Advil		
ction F - About the Person I	illing Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	-	
State/Province	WIE .	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		

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Department

Reporter Speciality

Today's date	10-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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## REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-11

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

(b) (6)

(max length: 50 characters)

Voluntary

Regulatory Status

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

## Contact Information - Sender

**Organization Name Confirm Email First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> Phone Email (If prefilled, changing this email address will not change your Login email ID) Country United States Street Address Line 1 Street Address Line 2 <blank>

City/Town (b) (6

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that

Citizen Type (select all that Consumer apply)

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

Yes

# **Problem Summary**

Problem Start Date 03/28/2019
Problem End Date 03/30/2019

**Please describe the health** Seizure from SALT vapor juice that was not told to me that you can not **problem or product problem.** use with a regular vape. I could not breathe after taking a drag, passed

The Attachments page will accept uploads of any records, pictures, or other information.

out and husband woke me out of a snorting, gasping for breath and convulsing. I could hear him as if he was far away and woke out of it when he started shaking me. I happened again but he knew what to do. He started shaking me and I came out of it but do not remember the gasping like I did the first time. Happened twice because I did not know I was using the wrong type of vape juice for my vape. It was also too high of a mg.

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

Treatment Received (select all that apply)

None

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

Select Unit of Time

minute(s)

What is the current status of the health problem?

Recovered or Resolved

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Female

Pregnant No

Race (Select all that apply) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

Select Unit of Age

year(s)

Please list any known preexisting health problems for Bipolar Disorder the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Effexor Lamictal Adderol Ambian Abilify Clonopin

# What are the main symptoms or health problems?

Term describing the health problem

Seizure

## **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, <blank> electronic nicotine or vaping

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that

Nicotine, Flavor(s), Other

apply)

product

Describe other e-liquid

ingredients

SALT juice

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Candy or Chocolate

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown but I can get it.

When did the person purchase this product?

03/20/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

Manufacturer Investigation Information

#### **Tobacco Product Purchase Location**

Purchase Location Name EZFumes

Country United States

**Phone** (817) 685-0102

Street Address Line 1 2900 Hwy 121 STE 165

Street Address Line 2 <blank>
City/Town Bedford
State Texas

ZIP/Postal Code 76021

Web Address <br/> <br/>

Email Address <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

## **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

On average, how often is this tobacco product used? Every Day

Did the problem occur with first time use of the tobacco No

product?

How long has the person been using this type of 4 tobacco product? Select Unit of Measure Day(s)

How soon after the tobacco product was last used did 30 the problem occur?

Select Unit of Measure Second(s)

How long has the person been using this particular brand or label?

Select Unit of Measure Day(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

## **Tobacco Product Parts**

## Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

#### Other Tobacco Products

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-liquid, e-juice or vape juice (purchased separately)

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

unknown but I can get it. I still have it at home. It was 30 mg SALT juice. I have not used it in 11 days so I have to say yes but I do not touch that anymore.

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

Every Day

#### Other Tobacco Products

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-liquid, e-juice or vape juice (purchased separately)

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown. I can get it though. I still use regular vape 12 mg but this was 30 mg SALT vape juice

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

Every Day

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. It was a store called Ezfumes in Bedford Texas that sold me the wrong product that made me have the seizure. I do not know what salesman, but it is a known fact that you can not use SALT vapor juice with a regular vape. Some other seizures reported may be a result of SALT vapor juice and that may need to be asked to others having seizures. I was informed of the difference from a different store. It was dangerous, obviously to sell it to me. Vapor stores should be obligated to watrn customers about the difference between them and that the different juices require different OHM's to be safe.

## **Attached Files**

None

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0.010 0010	ails		W. T	0.000
ompany l	Jnit	CDER-CTU	Originating Account	FAERS
ource Me	dium	MWO (Drug)	Source Form Type	E2B XML 3500B
riority		Routine		
verride A	uto Calculation Rule	No		
DA Recei	ved Date	11-Apr-2019	CTU Received Date	11-Apr-2019
CTU Triage Date			CTU Data Entry Date	
Report Typ	pe e	Spontaneous	Report Classification	Drug
ssign To		User		
Jser/Group	)			
orward to	Department	CDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priori	ity	Direct	52 1108 010@idaz.iiilo.gov/ (225/	
Case Reporter	First Name	Last Name	Email Address	Phone
ection A What ki	- About the Problem nd of problem was it? all that apply)	Were hurt or had a bad	side effect (including new or worsening sympto	oms)
ection A What ki (Check	- About the Problem nd of problem was it? all that apply)	Were hurt or had a bad Used a product incorrect Noticed a problem with		
What ki (Check	- About the Problem nd of problem was it? all that apply) e problem occurred	Were hurt or had a bad Used a product incorrec Noticed a problem with	tly which could have or led to a problem	
What ki (Check	- About the Problem nd of problem was it? all that apply) e problem occurred	Were hurt or had a bad Used a product incorred Noticed a problem with Had problems after swit 10-Jan-2019 Yes Hospitalization - admitte Required help to preven Disability or health prob Birth defect Life-threatening Death	tly which could have or led to a problem the quality of the product ching from one product maker to another make and or stayed longer of permanent harm	
Date the Serious Did any (Check	- About the Problem nd of problem was it? all that apply)  e problem occurred  of the following happen? all that apply)  erious/important medical (Please Describe Below)	Were hurt or had a bad Used a product incorred Noticed a problem with Had problems after swit 10-Jan-2019 Yes Hospitalization - admitte Required help to prever Disability or health problems after swit Life-threatening Death Other serious/important Seizures	the quality of the product the quality of the product ching from one product maker to another make and or stayed longer at permanent harm lem	er
Date the Serious Did any (Check  Other seincident	- About the Problem nd of problem was it? all that apply)  e problem occurred  of the following happen? all that apply)  erious/important medical (Please Describe Below)	Were hurt or had a bad Used a product incorrect Noticed a problem with Had problems after swit 10-Jan-2019 Yes Hospitalization - admitte Required help to prever Disability or health problems in the defect Life-threatening Death Other serious/important Seizures	tly which could have or led to a problem the quality of the product ching from one product maker to another make and or stayed longer of permanent harm	er

levant Test/Laboratory Data		1 of 1
Test Name	Test Date	10-Jan-2019
Test Result	Test Unit	
Low Test Range	High Test Range	

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	More Information Available?				
Ac	lditional Comments				
		was called. She came to with	h no recollection of the in	round in a full seizure. She was ncident, high blood pressure and horrible ssues it took her a long time to calm	
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about				
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	0			
	Name of the company that makes (or compounds) the product	Print stick MOD vape			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmac Generic Biosimilar	y or an Outsourcing Facility		
	Strength	Other	If Other	50 of nicotine vap	111
Ħ	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				44
	Lot number				
	Dosage Form		V		
	Quantity		If Other		1
H	Frequency		If Other		1
	How was it taken or used	Respiratory (inhalation)	If Other	-4 .4	
	Date the person first started taking or using the product  Date the person stopped taking or using the product				

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	Give best estimate of duration	) i	
	Is therapy still on-going?		
W		oduct? (such as what condition was it supposed to treat) 1 of 1	
H			
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that		
04	makes the medical device		
lo	ner identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		Ц
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the		
	medical device when the problem occurred?		
= 0	er implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
	ate the implant was put in	Date the implant was taken out (If	
	ato mpiane mao paem	relevant)	
Se	ection E - About the Person Wh	o Had the Problem	
	Person's Initials	Miles	
	Gender	Female	
	Age (specify unit of time for age)	16 Year(s)	П
	Date of Birth		Ħ
	Weight	49.5 kg	П
П	Ethnicity (Choose only one)	Not Hispanic/Latino	П
	Race (Check all that apply)	American Indian or Alaskan Native	Ħ
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	-

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

NA		
ease list all allergies (such	as to drugs, foods, pollen or others)	
NA		
t and other immedent in far	notion about the narrown (such as ampling programs), placks	Luca eta \
t any other important infor	nation about the person (such as smoking, pregnancy, alcoho	i use, etc.)
all current prescription m	edications and medical devices being used.	
None		
all array that acrossos mad	astions and any situating uninquals as unlamante and bankals	wanaadiaa bairaa waad
	cations and any vitamins, minerals, supplements, and herbal i	emedies being used
None		
ction F - About the Persor	Filling Out This Form	1 of 1
Primary?	Yes	1011
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	1018	
City		
State/Province	(b) (6)	
Country	(b) (6)	
ZIP or Postal code		
Telephone number		
Email address		
Fax		
3000		
Reporter Organization		

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Department

Reporter Speciality

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Today's date	11-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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CTU No.: FDA-CDER-CTU-2019-(6) (6) | Department: CTP | RCT No.: RCT-(5) (6) | CTU Triage Date: 11-04-2019 | Total Pages:

Basic Deta	ails					
Company L	Jnit	CDER-CTU	Originating Account	FAERS		
Source Medium		MWO (Drug)	Source Form Type	E2B XML 3500B		
riority		Routine				
Override A	uto Calculation Rule	No				
FDA Recei	ved Date	11-Apr-2019	CTU Received Date	11-Apr-2019		
CTU Triage	e Date		CTU Data Entry Date			
Report Typ	е	Spontaneous	Report Classification	Drug		
Assign To		User				
User/Group	<b>D</b>	G = _				
Forward to	Department	CDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)			
Case Priori	ty	Direct	3 /1 /			
Contact						
Case	First Name	Last Name	Email Address	Phone		
Reporter						
$\mathbf{Z}$	(b) (6)	(b) (6)	(b) (6)	(b) (6)		
		Noticed a problem with the quality of the product  Had problems after switching from one product maker to another maker				
Date the	e problem occurred					
Serious		No				
	of the following happen? all that apply)	Hospitalization - admitte Required help to prevent Disability or health proble Birth defect Life-threatening Death	t permanent harm			
		Other serious/important	medical incident(Please Describe Below)			
	hat happened and how onal documents if nece		le as many details as possible F	DA may reach out to you fo		
ACCOUNT OF THE PARTY OF THE PAR	e of the exact date but son		I had the first of 3 mild seizures I be			
Not sure years of time sto point. It device I seek me	d and never had one until pped for a few seconds. It was vaping 18 mg at that t was using is a Smok Alie	My hearing became fuzzy ime and have since low n 220W and I was vapin	nly lasted a few seconds but I felt like y, my eyes dazed and then I felt like ered to 12 mg and have not had that g MBYC 18mg that I purchased from pout it so he could keep an eye on m	I woke up and was okay at that occur again since then. The www.gaintvapes.com I did not		

elevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	

CTU No.: FDA-CDER-CTU-2019-01 (5) | Department: CTP | RCT No.: RCT (b) (6) | CTU Triage Date: 11-04-2019 | Total Pages: 5

	More Information Available?				
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ection C - About the Products			-	1 of 1
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			40
	This report is about	Drug			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	MBYC Vapor			
	Name of the company that makes (or compounds) the product	Purchased from www.g	gaintvapes. com		
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharm Generic Biosimilar	nacy or an Outsourcing Facili	У	
	Strength	18 mg milligram(s)	If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	No			
Dr	ug Therapy				1 of 1
11	Expiration date				
	Lot number				
1	Dosage Form			y .	
1-1	Quantity		If Other		
	Frequency	As needed	If Other		4
	How was it taken or used	Other	If Other	Vaping	
	Date the person first started taking or using the product				
	Date the person stopped taking				

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	Give best estimate of duration	· ·	H
	Is therapy still on-going?		
W	The recent of the second of th	oduct? (such as what condition was it supposed to treat) 1 of 1	
	alternative to smoking		
	Returned to Manufacturer On		
Se	ection D - About the Medical De	vice	
	Name of medical device		
	Name of the company that makes the medical device		
Ot	ther identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	or implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	o Had the Problem	
	Person's Initials	OUR .	
	Gender	Female	
	Age (specify unit of time for age)	55 Year(s)	П
	Date of Birth		
	Weight		
	Ethnicity (Choose only one)	Hispanic/Latino	
	Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American	

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

	none	
Р	lease list all allergies (such as to drugs, foods, pollen or others)	
	none	
	none	
Li	st any other important information about the person (such as smoking, pregnancy, alcohol	l use, etc.)
THE		
L	st all current prescription medications and medical devices being used.	-
	Rosuvastatin calcium 5 mg and Levothyroxine 150 MCG Vitamin D3 2,000	
Li	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal r	emedies being used.
	Rosuvastatin calcium 5 mg and Levothyroxine 150 MCG Vitamin D3 2,000	
6		

tion F - About the Persor		1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(A) (B)	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		

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Today's date	11-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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CTU No.: FDA-CDER-CTU-2019-101 (3) | Department: CTP | RCT No.: RCT | CTU Triage Date: 12-04-2019 | Total Pages:

# 9 MedWatch 3500 Health Professional Report

The FDA Safety Information and Adverse Event Reporting Program

FDA Safety Report ID #	FDA Received Date 11-Apr-	2019	
A. PATIENT INFORMATION			
A1. Patient Identifier:			
A2. Age:	16	Year(s)	
A2. Date of Birth:			
	Female		
	Male	Yes	
A3. Gender:	Intersex		
	Transgender		
	Prefer not to disclose		
A4. Weight:	65	kg	
	Hispanic/Latino		
A5. Ethnicity:	Not Hispanic/Latino	Yes	
	Asian		
	American Indian or Alaskan Native		
A6. Race:	Black or African American	Yes	
	White		
	Native Hawaiian or Other Pacific Islander		
B. ADVERSE EVENT, PRODUCT PROBLEM	*		
D. 100 100 100 010 010 13 121 15 10 10 10 10 10 10 10 10 10 10 10 10 10	Adverse Event	Yes	
	Product Use/Medication Error		
B1. Type of Report:	Product Problem (e.g., defects/malfunctions)		
	Problem with Different Manufacturer of Same Medicine		
	Death (Date of Death)		
	Life-threatening		
	Hospitalization (initial or prolonged)	11 1	
B2. Outcome Attributed to Adverse Event:	Disability or Permanent Damage		
	Congenital Anomaly/Birth Defects		
	Other Serious or Important Medical Events	Yes	
	Required Intervention to Prevent Permanent Impairment/Damage	Yes	
B3. Date of Event:	23-Mar-2019		
B4. Date of this Report:	11-Apr-2019	11-Apr-2019	

Describe Event, Problem or Product Use/Medication E	and 4/5/19, both about 30-45 minutes after vaping with Juul. The seizures required visits to the hospital, and adjustment of his daily
ige young man win epilepsy, on medicalion, expendiced breakin ough sezures on 3/23/19 an ntative medication.	ind 4-0/18, point about 50-45 filliples after valying with duti. The seconds required visits to the hospital, and adjustment of his daily.

CTU No.: FDA-CDER-CTU-2019-10110 | Department: CTP | RCT No.: RCT D) (6) | CTU Triage Date: 12-04-2019 | Total Pages: 9

B6. Relevant Tests/Laboratory Data:	
Test 1	
Test Date:	
Test Name:	
i estivanie.	
	— I
Test Result:	
1311/213/6	
7.7107	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 2	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	<del></del>
Low Test Range:	
High Test Range:	
Test 3	
Test Date:	
Test Name:	
l estivante.	
Test Result:	
1,000,000	
7.0126	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 4 Test Date:	
Test Date.	
Lagran and the second s	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

CTU No.: FDA-CDER-CTU-2019-(D) (6) Department: CTP | RCT No.: RCT-(D) (6) | CTU Triage Date: 12-04-2019 | Total Pages: 9

B6. Relevant Tests/Laboratory Data:	
Test 5	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 6	V.
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 7	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 8	V
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
	II -

normal labs at time of seizure, except glu	ose slightly elevated as expected	
7. Other Relevant History, In-	luding Preexisting Medical Conditions:	
rimary generalized epilepsy		

CTU No.: FDA-CDER-CTU-2019-101/10 | Department: CTP | RCT No.: RCT-10) (6) | CTU Triage Date: 12-04-2019 | Total Pages: 9

C. PRODUCT AVAILABILITY				
C1. Product Available for Evaluation?	No			
C1. Returned to Manufacturer on:	1000			
C2. Do you have a picture of the product?				
	<u>U</u>			
D. SUSPECT PRODUCTS				
Product 1				
D1. Does this report involve cosmetic, dietary supplement or food/medical food?				
D1. Name:	JUUL ENDS (electronic nicotine delivery system	n)		
D1. Strength:	one	D	F	
D1. Manufacturer/Compounder:	Juul			
D1. NDC # or Unique ID:	unknown			
D1. Lot #:				
D2. Dose or Amount:				
D2. Frequency:				
D2. Route:				
	Start 23-Mar-2019	Stop	11-Apr-2019	
D3. Treatment Dates/Therapy Dates:	Give best estimate of duration			
Contraction Contraction in America	Is therapy still on-going?		1	
D4. Diagnosis for Use:	is an apply among gaining			
13.77 C 20.70 C 13.70	OTC (Over-the-counter)		Ť T	
77.7	Compounded			
D5. Product Type:	Generic			
	Biosimilar			
	Biosimilar		L.	
D6. Expiration Date:				
D7. Event Abated After Use Stopped or Dose Reduced?	Yes		=	
D8. Event Reappeared After Reintroduction?	Yes			1.0
Product 2 D1. Does this report involve cosmetic, dietary supplement or food/medical food?				
D1. Name:				
D1. Strength:				4
D1. Manufacturer/Compounder:				
D1. NDC # or Unique ID:				
D1. Lot#:				
D2. Dose or Amount:				
D2. Frequency:				
D2. Route:				
T.	Start	Stop		
D3. Treatment Dates/Therapy Dates:	Give best estimate of duration	10-10-6	1	
	Is therapy still on-going?		11/2	
D4. Diagnosis for Use:				_
or sugnition to to to	OTC (Over-the-counter)			
A AC ATTO	Compounded			
D5. Product Type:	Generic			
D6. Expiration Date:	Biosimilar			
	Distribut			
D7. Event Abated After Use Stopped or Dose Reduced?				
D8. Event Reappeared After Reintroduction?				

CTU No.: FDA-CDER-CTU-2019-10) (6) | Department: CTP | RCT No.: RCT-(b) (6) | CTU Triage Date: 12-04-2019 | Total Pages: 9

E. SUSPECT MEDICAL DEVICE	7		
E1. Brand Name:			
E2a. Common Device Name:	Juur		
E2b. Procode:			
E3. Manufacturer Name, City and State:	41		
E4. Model #:			
E4. Catalog #:			
E4. Serial #:			
E4. Lot #:			
E4. Expiration Date:			
E4. Unique Identifier (UDI) #:			
	Health Professional		
E5. Operator of Device:	Patient/Consumer	_	
	Other		
E6a. If Implanted, Give Date:			-
E6b. If Explanted, Give Date:			
E7a. Is this a single-use device that was reprocessed and reused on a patient?			
E7b. If Yes to Item 7a, Enter Name and Address of Reprocessor:			
E8. Was this device serviced by a third party servicer?			

04.44 0040	Therapy End Date
04-Mar-2019	11-Apr-2019

CTU No.: FDA-CDER-CTU-2019(6) | Department: CTP | RCT No.: RCT-(b) (6) | CTU Triage Date: 12-04-2019 | Total Pages: 9

G. REPORTER		
	Last Name	(a) (b)
G1. Name and Address	First Name	(b) (6)
	Address	(b) (6)
	City	(b) ( <del>§</del> )
	State/Province/Region	8
	ZIP/Postal Code	(O) (\$
	Country	US
	Phone #.	(b) (6)
	Email:	(b) (6)
G2. Health Professional?	Yes	
G3. Occupation:	Physician	
G4. Also Reported To:	Manufacturer/Compounder	
	User Facility	
	Distributer/Importer	11 (1)
G5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box (Confidentiality Requested):	No	



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-13

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	        
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	        
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Mother

# **Problem Summary**

**Problem Start Date** 04/11/2019 **Problem End Date** 04/11/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

My daughter had a seizure after using a Suorin Air V2 Ultra Vape device containing 0.5 mg strength nicotine. She took two hits and seizured about 5-8 minutes later for a length of 3 to 4 minutes

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

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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

hour(s)

Select Unit of Time

What is the current status of the health problem?

Recovered or Resolved

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

Gender Female

Pregnant No

Race (Select all that apply) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem

**b**) (6)

Age of the person when the problem occurred

Select Unit of Age

year(s)

Please list any known preexisting health problems for none the affected person

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Occasional iron supplement

# What are the main symptoms or health problems?

Term describing the health problem

Seizure grand mal

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

electronic nicotine or vaping Rechargeable product, Uses a tank or tank system

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

for your electronic cigarette, Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the

Nicotine, Flavor(s)

following? (select all that apply)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Menthol

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Suorin Air V2 Ultra-Portable System

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog

<blank>

number, manufacturing date/ batch code)

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

From a Friend

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Rarely

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

<blank>

Select Unit of Measure

<blank>

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

Select Unit of Measure

Minute(s)

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

Full Tobacco Product Part Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

SuorinUSA Air V2 Ultra-portable system

**Tobacco Product Part Type** 

Battery(reusable)

When was this tobacco product part purchased or acquired?

chased or <blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Any other identifying tobacco product part codes(e.g. SKU, item/catalog number)

<blank>

What is the country of manufacture of the tobacco product part?

United States

Where is the tobacco product part now?

User/Consumer has the product

Do you know who manufactured this tobacco product part?

Yes

#### **Tobacco Product Part Purchase Location**

How was this tobacco product part acquired?

From a Friend

**Purchase Location 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>

**Email Address** 

<blank>

#### **Tobacco Product Part Manufacturer Information**

Manufacturer Name

<blank>

State

<blank>

State/Province

<blank>

# **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### **Other Tobacco Products**

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. My daughter had tried other e-cigarette products in the past, but is not a regular user. This seizure was a truly scary event for everyone involved. I was not a witness to the event, but her friends said her lips turned blue (cyanotic) and lasted between 2-4 minutes. For a couple hours afterwards, she was lethargic, disoriented, and kept forgetting what had happened.

#### **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-16

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Out of the first Name	113513
Organization Name	        
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<black></black>
Job Title	        
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	<black></black>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Father

# **Problem Summary**

Problem Start Date 11/22/2017

Problem End Date 11/24/2017

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other

My son had a seizure after inhaling from a Juul vaping product

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

information.

Lasting disability or other permanent health problem, Life threatening, Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

My son was hospitalized for 3 days to be assessed for a seizure after inhaling a Juul vaping product.

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Male

Race (Select all that apply)

White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the 16

problem occurred

Select Unit of Age year(s)

Please list any known preexisting health problems for None the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

## What are the main symptoms or health problems?

Term describing the health problem

Epilepsy grand mal

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** 

vaporizer

Select all that apply to Disposable (non-refillable) product, Rechargeable product, Uses the electronic cigarette, prefilled cartridge, cart, cartomizers or carto. electronic nicotine or vaping

product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, <blank> electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Propylene Glycol

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name. including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

11/22/2017

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

Juul

What is the country of manufacture of the tobacco product?

United States

Where is the tobacco product now?

Unknown

How was this product acquired?

From a Friend

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Rarely

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco Yes product?

How long has the person been using this type of tobacco product?

<blank>

Select Unit of Measure

<blank>

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

<blank>

Select Unit of Measure

Hour(s)

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

## **Tobacco Product Parts**

#### **Other Products Used**

Has the affected person used other tobacco products No (either currently or in the past)?

#### Other Tobacco Products

#### Additional Information

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

Juul vaping caused my son's seizure

problem. Attachments may be added on the next page.

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-16

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# **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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	        
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	   
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Other
Describe other consumer/ concerned citizen type	Parent
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Mother

## **Problem Summary**

Problem Start Date

12/08/2014

**Problem End Date** 

12/08/2014

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

We saw that your organization is looking into vaping causing seizures. I wanted to share my son's story with you in order to help with your investigation. After coming into contact with vaping juice, staying up all night, and drinking too much caffeine the next day had a tonic seizure. I realize that there are many seizure triggers on this list but as a result of these bad decisions on this school trip had to be on seizure medication for 4 years. He has not had another seizure since and is now off of the medication which is a blessing as the medication made him mentally foggy.

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

Lasting disability or other permanent health problem

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

The emergency room performed tests. I will upload these. He also had an EEG which was normal and then recently another EEG which also was normal.

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a

User(s)

separate report for each affected person, if possible.)

How many users were

affected?

1

Gender Male

Race (Select all that apply) White

**Ethnicity** Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the

problem occurred

17

Select Unit of Age year(s)

Please list any known preexisting health problems for the affected person

had one seizure after falling while snow skiing when he was 11. He was not on any anti seizure medication.

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

None

# What are the main symptoms or health problems?

Term describing the health problem

Tonic seizures

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping <blank> product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

<blank>

Was the e-liquid dripped on to the atomizer or heating element?

<blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

I do not know the product name as Justin was sharing another kid's vaping unit.

When did the person purchase this product?

<blank>

**UNIVERSAL PRODUCT** CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product

acquired?

<blank>

Do you know where the product was purchased?

<blank>

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

## **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

<blank>

On average, how often is this tobacco product used?

<blank>

Are other substances being mixed in with the tobacco product when used?

<blank>

Did the problem occur with first time use of the tobacco product?	<blank></blank>
How long has the person been using this type of tobacco product?	<blank></blank>
Select Unit of Measure	<blank></blank>
How soon after the tobacco product was last used did the problem occur?	<blank></blank>
Select Unit of Measure	<blank></blank>
How long has the person been using this particular brand or label?	<blank></blank>
Select Unit of Measure	<blank></blank>
Did the person continue to use this tobacco product after the problem occurred?	<blank></blank>
Did this same or similar problem happen again after repeat use of the tobacco product?	<blank></blank>
Did the person change	

## **Tobacco Product Parts**

before using it (for example, <blank>

the product in any way

removing a filter from a

cigarette)?

## **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

## **Other Tobacco Products**

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

I am adding an attachment that has notes about the event.

#### **Attached Files**

FILENAME (b) (6) 2nd Seizure Records.pdf

**Description of Attachment** Seizure Records

Attachment Type Other

#### United States Food and Drug Administration Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 04/17/2019

COMPLAINT

# (b) (6

Complaint Receiving Accomplishing How Complaint Complaint Complaint Date Organization District Received Source Received By

04/15/2019 NYK-DO SAN-DO Telephone Friend/Relative Allen, Vera L Pending at Branch

of Consumer

Life Threatening

Injury/Illness

**Complainant Identification** 

Name Address

(b) (6)

Phone (W) Phone (H) Source POC Name Source Phone

(b) (6)

Complaint/Injury

Complaint Description Adverse Event Adverse Event Injury / Illness Result Date

Complainant called on behalf of her 23 year old son who has no known allergies and had no medical conditions. He started using Juul E-Liquid Pods in 2018. Per complainant, he used them all day and all night daily however she does not know what flavors only that he used "some kind of oil with CBD". On 02/17/19 he experienced a seizure. He was treated and released. He continued use of product. On 04/02/2019 he experienced a second seizure and injured his back during the incident. Nicotine poisoning test was ordered. No results yet. Complainant believes his symptoms are directly related to product in question based on report released by FDA.

Notify DEIO/EMOPS	Notification	Attended Health Professional?		Emergency Room /		Need addnl.
Yes	04/15/2019		No	No.	Not	1DA Contact.

Reported to Manufacture

02/17/2019

Seizures

r

Remarks

**Complaint Symptoms** 

Sympton	System Affected	Onset Time	Duration	Remarks
Seizures/convulsions	NERVOUS	12 Months	Persists	First on on 2/17/19, Second one one 4/2/19
NEC - Identify in Remarks	NEC	12 Months	Persists	Injured back during seizure

Health Care Professional

Provider Name Address Phone Occupation

Ellis Hospital 1101 Nott Street Schenectady NY 12308 (518) 243-4000 Medical Doctor (MD)

Date: 04/17/2019 Page: 1 of 3



Headquarters

**Hospital Information** 

Hospital Name Address Phone Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name Address Phone ER Date

**Product and Labeling** 

Brand Name Product Name Product Code Product Description PAC UPC Code

Juul E-Liquid Pods 98LAA01 E-Cigarette; Unflavored; For 96R801 UNK

Consumer Use

Qty / Unit / Package Lot/ Exp/Use Purchase Product Amount

Serial# by Date Date Used Consumed/Used

1 Count Other, UNK N/A 2018 Yes UNK

identify in Label Remarks

Date Date Amount Imported Country of Label
Used Discontinued Remained Product? Origin Remarks

2018 - 04/2019 NONE No United States Packaging discarded.

04/2019 Product codes not available

Retail Problem Ingredient Group

Name Address

Manufacturer/Distributor

FEI Name & Address Home District Firm Type

3013660768 Juul Labs, Inc. 560 20th St San Francisco California United States SAN-DO Corporate

94107-4344

Initial Evaluation/Initial Disposition

Problem Keyword Problem Keyword Details

Reaction Seizures, injured back

Initial Evaluation Initial Disposition Disposition Made By Disposition Date

FDA Action Indicated Referred to Other FDA District Allen, Vera L 04/15/2019

**Initial Disposition Remarks** 

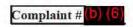
There was difficulty reporting via SRP

Referrals

Org Name HHS Mail Code

SAN-DO HFR-PA100

Date: 04/17/2019 Page: 2 of 3



There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

Complaint #(b) (6)

#### COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Operation Assignment Accomplishing Performing Sample PAF Status Status Id Code Number Organization Organization Number Date

There are no Follow Up Operations related to this complaint.

**Disposition Summary** 

Is Consumer Responsible Address Name Firm Type

Responsible? FEI

Follow-Up Disposition Disposition Made By Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name HHS Mail Code

Date: 04/17/2019 Page: 3 of 3

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 to (6) | Department: CTP | RCT No.: RCT-(9) (6) | CTU Triage Date: 17-04-2019 | Total Pages;
5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		The second second	2000
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	1	, t
Override Auto Calculation Rule	No		
FDA Received Date	17-Apr-2019	CTU Received Date	17-Apr-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact	Contract of the Contract of th	200000	0.000	
Case Reporter	First Name	Last Name	Email Address	Рһопе
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A -	About the Problem	100		
	nd of problem was it? all that apply)	Used a product incorrectly w	effect (including new or worsening symptom hich could have or led to a problem uality of the product g from one product maker to another maker	ns)
Date the	problem occurred	10-Mar-2019		
Serious		Yes		
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important med	The state of the s	
	rious/important medical Please Describe Below)	I had a Seizure		
I.Tell us w anv additio	hat happened and how nal documents if nece	ı it happened (Include a ssarv)	is many details as possible FE	OA may reach out to you for
I had a s	seizure the morning after a	night of vaping. I had one	a year ago after the same but at th bing more than my normal (small) a	

televant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019-101 (6) | Department: CTP | RCT No.: RCT-10) (6) | CTU Triage Date: 17-04-2019 | Total Pages: 5

	More Information Available?				
Ac	dditional Comments				
Se	ection B - Product Availability	-			
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
11	Туре	Drug/Biologic			1 121
	This report is about	Cosmetic, Dietary Supplement	ent or Food/Medicinal Food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Jaul			
	Name of the company that makes (or compounds) the product	Juul			
1	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar	or an Outsourcing Facility		
	Strength	3 or 5 units if nicotine mg milligram(s)	If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Yes			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				111
	Dosage Form		Tyzyani		
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product				

Generated by: SYSTEM 17-Apr-2019 18:45:37 Page 2 of 5 Generated on:

Receipt No: RCT-(b) (6) FDA 3500B Form
CTU No.: FDA-CDER-CTU-2019 (6) Department: CTP | RCT No.: RCT-(b) (6) | CTU Triage Date: 17-04-2019 | Total Pages:

Date the person stopped taking or using the product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 Help to stop smoking Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number **UDDI Number** Expiration date Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Gender Female Age (specify unit of time for age) 45 Year(s) Date of Birth Weight 96.3 kg Not Hispanic/Latino Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American

Generated by: SYSTEM Generated on: 17-Apr-2019 18:45:37 Page 3 of 5

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
Diabetes
Please list all allergies (such as to drugs, foods, pollen or others)
Penicillin, sulfa based medication
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
Was taking Welbutrin at the time of both seizures, but only had them after heavy vaping.
List all current prescription medications and medical devices being used.
Fluoxetine 40mg, Nova Log insulin, Basalgar Insulin 30 units, Escitalopram 5mg, Atavan .5 mg & 500 mg Keppra ( only since the second seizure).
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
Vitamins C, B12, D, & calcium

tion F - About the Persor	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title	deco.	
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(0.10)	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		

Generated by: SYSTEM Generated on: 17-Apr-2019 18:45:37 Page 4 of 5

FDA 3500B Form
CTU No.; FDA-CDER-CTU-2019 (6) | Department: CTP | RCT No.; RCT (D) (6) | CTU Triage Date: 17-04-2019 | Total Pages;
5

Department		
Reporter Speciality		
Today's date	17-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM 17-Apr-2019 18:45:37 Page 5 of 5 Generated on:



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-20

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## Report Identifying Information

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Voluntary

Type of Submission

**Regulatory Status** 

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	        
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	        
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer, Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Mother

# **Problem Summary**

Problem Start Date 12/19/2018
Problem End Date 12/19/2018

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

(b) (6) took a "big rip" on his cool mint flavored Juul - that was the last thing he remembered about the incident. He had a grand mal seizure and was transported to the emergency department.

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

Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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

5

Select Unit of Time

month(s)

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender

Male

Race (Select all that apply)

White

**Ethnicity** 

Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

29

Select Unit of Age

year(s)

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

500mg 2x day Divalproex ER (generic Depakote)

## What are the main symptoms or health problems?

Term describing the health problem

Seizure grand mal

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

Other

Describe other electronic cigarette, electronic nicotine Juul Cool Mint or vaping product subtype

Select all that apply to the electronic cigarette, product (including electronic

electronic nicotine or vaping Uses prefilled cartridge, cart, cartomizers or carto.

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

waterpipe)

Purchased in a non-refillable disposable cartridge

electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Other

Describe other e-liquid ingredients He used a Juul cool mint cartridge, unmodified. We're not sure what's in ...

it

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Mint (such as wintergreen or spearmint)

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul Cool Mint

When did the person purchase this product?

12/12/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

123456789123

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying

tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

We don't have the bar code from the product. He and his fiance believed that the Juul caused his seizure - it was so immediate and uncommon-- and so they threw the product out.

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location 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> **Email Address** <blank>

#### **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco No product when used?

Did the problem occur with first time use of the tobacco product?

No

How long has the person been using this type of tobacco product?

2

Select Unit of Measure

Year(s)

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

1

Select Unit of Measure

Second(s)

How long has the person been using this particular brand or label?

6

Select Unit of Measure

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

## **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products

(either currently or in the past)?

#### Other Tobacco Products

Tobacco Product Type Cigarette

Tobacco Product Subtype <blank>

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

unknown

Is the tobacco product currently being used?

No

#### Other Tobacco Products

Tobacco Product Type

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype <blank>

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

unknown

Is the tobacco product currently being used?

No

#### Additional Information

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. The trip to the emergency department was expensive - fortunately he has insurance but there were a lot of covered and additional expenses. As a result of the seizure his physician increased his seizure medication, which none of us liked because there are side effects to that medication. The seizure itself was really scary and his fiance and her 7-year old son witnessed it which was traumatic for them.

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-21

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## 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?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside SRP)? No

Describe who the problem was reported to

<blank>

#### Contact Information - Sender

Sender Category Consumer/Concerned Citizen (FdaTPR)

## **Problem Summary**

Product Problem Type (select all that apply)

Other

Describe the other product problem

2 nicotine poisoning seizures cause by excessive juul use.

In what setting(s) did this problem occur? (select all that apply)

One person using one or more product(s), Public indoor location (office, store, mall, restaurant, bar, school, sports arena)

Problem Start Date 06/27/2018
Problem End Date 04/16/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information. I have had 2 separate 10 minute seizures at work from excessive juul use and what I believe is nicotine poisoning. I was able to sneak the juul in the office, bathroom, desk etc. and was going through upwards of 1 5% Virginia tobacco juul pod a day when both seizures happened. I have had an MRI, CAT scan, EEG and all were inconclusive of epilepsy. I am quitting my juul habit with the help of my doctor in the hopes that the seizures will stop.

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

<blank>

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Discharged from the emergency room after 4 hours.

How long did the health problem last (if resolved), or

10

(if ongoing) how long has it lasted so far?

Select Unit of Time minute(s)

What is the current status of the health problem?

Recovered or Resolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Male

Race (Select all that apply) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the

problem occurred

23

Select Unit of Age

Please list any known preexisting health problems for the affected person

None

year(s)

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

2 Onnit alpha brain supplement pills daily

## What are the main symptoms or health problems?

Term describing the health problem

Seizure grand mal

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge, Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

Describe other e-liquid ingredients

<blank>

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Tobacco

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Altria - Juul - Virginia tobacco flavored 5% nicotine juul pods

When did the person purchase this product?

04/15/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the

Don't Know

"UL" symbol?

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code) What is the country of

manufacture of the tobacco United States

product?

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

Other

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location Name** <blank>

Country <blank>

Phone <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank> City/Town <br/>
State <br/>
ZIP/Postal Code <br/>
Web Address <br/>
Email Address <br/>
State <br/>
<br/>
State <b

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) <blank>

Country <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

Phone <br/> <br/>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <black>

State <br/> <br/>

ZIP/Postal Code <br/>
<b

Web Address <br/> <br/>

Email Address <br/> <blank>

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

Yes

Describe what substances are being mixed with the tobacco product

Alcohol, marijuana

Did the problem occur with	
first time use of the tobacco	No
product?	

How long has the person been using this type of tobacco product?

Year(s)

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

Select Unit of Measure

10

Select Unit of Measure Minute(s)

How long has the person been using this particular brand or label?

Select Unit of Measure

Year(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

#### **Other Tobacco Products**

Tobacco Product Type Chewing tobacco (loose leaf chew, plug, twist/roll)

Tobacco Product Subtype Other

Description of other tobacco product subtype

Nicotine salt

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Zyn wintergreeen 6mg pouches

Is the tobacco product currently being used?

No

### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

I have had 2 separate 10 minute long seizures in Denver Colorado, June 2018 and April 2019 directly caused by nicotine poisoning. I can attest to my usage, frequency, and intensity of seizures as well as the role of the Juul. Please contact me at (b) (6)

### **Attached Files**

None



#### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-22

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Regulatory Status Voluntary

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside SRP)? No

Describe who the problem was reported to

<blank>

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

**Organization Name** <blank> **Confirm Email** (b) (6) **First Name Last Name** Did you report the problem No to the manufacturer? Job Title <blank> Phone Email (If prefilled, changing this email address will not (b) (b) change your Login email ID) **United States** Country Street Address Line 1 Street Address Line 2 <blank> City/Town State ZIP/Postal Code **Sender Category** Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Concerned citizen apply) Are you the person who experienced health No problems associated with a tobacco product? Describe your relationship to the person who Father experienced the health

# **Problem Summary**

problem

**Problem Start Date** 04/13/2019

**Problem End Date** 04/13/2019

Please describe the health problem or product problem.

The Attachments page will accept uploads of any records, pictures, or other information.

My son stated he woke up and "hit" his Juul, and had a seizure within a few minutes after that.

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

<blank>

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

He received an EKG, CT Scan, and an EEG a few days later. The EEG resulted in a diagnosis of epilepsy, which was today, but he just told me that he did not tell any medical professionals involved that he had the seizure immediately after hitting the Vuse.

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

Select Unit of Time minute(s)

What is the current status of the health problem?

Recovered or Resolved

### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Male

Race (Select all that apply)

White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

18

Select Unit of Age year(s)

Please list any known preexisting health problems for None the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

None

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** 

vaporizer

Select all that apply to Rechargeable product, Uses prefilled cartridge, cart, cartomizers or the electronic cigarette, electronic nicotine or vaping

product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

for your electronic cigarette, Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown - Vuse is the only name I know

When did the person purchase this product?

04/13/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

111111111111

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

Unknown

What is the country of manufacture of the tobacco product?

United States

Where is the tobacco product now?

Unknown

How was this product acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

R.J. (RJ) Reynolds Tobacco Company

# **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is Some Days this tobacco product used?

Are other substances being No mixed in with the tobacco

product when used?

Did the problem occur with first time use of the tobacco No

product?

How long has the person been using this type of tobacco product?

Select Unit of Measure

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

Select Unit of Measure

Year(s)

5

Second(s)

How long has the person been using this particular brand or label?

1

Select Unit of Measure

Day(s)

Did the person continue to use this tobacco product after the problem occurred?

Unknown

Did this same or similar problem happen again after repeat use of the tobacco product?

No

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

### **Tobacco Product Parts**

### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

## Other Tobacco Products

**Tobacco Product Type** 

Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

Some Days

#### Other Tobacco Products

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

Some Days

### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. I honestly don't know many of the questions asked about this product. I know that he used to smoke cigarettes, switched to Juuls, went back to cigarettes because he said Juuls were to expensive. The Vuse did not belong to him, he was at his brother's house and had just woke up prior to using the device and the seizure immediately happening.

### **Attached Files**

None



#### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-24

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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

Health Problem associated with a tobacco product (not associated with

submitting? a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

### **Contact Information - Sender**

Organization Name <br/>
Confirm Email (b) (6)<br/>
First Name (b) (6)<br/>
Last Name (b) (6)

Last Name

Did you report the problem to the manufacturer?

Job Title <br/>
<b

Phone (b) (6)

Email (If prefilled, changing this email address will not change your Login email ID)

(b) (6)

Country United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned
Citizen Type (select all that Con

apply)

Consumer

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

Yes

# **Problem Summary**

Problem Start Date 01/01/2009

Problem End Date 04/24/2019

Please describe the health problem or product problem.

I had 2 seizures in 2014, which could not be explained at the time

The Attachments page will accept uploads of any records, pictures, or other information.

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

Lasting disability or other permanent health problem

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Many tests and blood work was done in 2014, but the doctors could not explain why the seizures happened.

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Male

Race (Select all that apply)

White

Ethnicity

<blank>

Birth date of the person who experienced the problem

(b) (0)

Age of the person when the problem occurred

58

Select Unit of Age

year(s)

Please list any known prethe affected person

existing health problems for High blood pressure, controlled by a doctor prescribed med.

### Medications and Supplements

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

metoprolol tartrate

# What are the main symptoms or health problems?

Term describing the health problem

Generalized epileptic seizure

### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping Puff/flow activated product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

Purchased in a non-refillable disposable cartridge, Mixed in a shop or on-line per request or "to order"

electronic nicotine or vaping product Describe the e-liquid mix unknown Does the e-liquid, e-juice or vape juice contain any of the Nicotine following? (select all that apply) Was the e-liquid dripped on to the atomizer or heating Unknown element? Full Tobacco Product Name, including Brand and Subunknown Brand (if unknown, please enter "unknown") When did the person 10/15/2012 purchase this product? UNIVERSAL PRODUCT <blank> CODE (UPC) from Label Does the involved product Don't Know device or package bear the "UL" symbol? Any other identifying tobacco product codes (for I do not have the product any longer, as I haven't vaped since January/ example, SKU, item/catalog Febuary 2013. number, manufacturing date/ batch code) What is the country of manufacture of the tobacco **United States** product?

Where is the tobacco product now?

Product was discarded

How was this product acquired?

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

**Purchase Location Name** Liquivape

Country United States

Phone <blank>

1214 Tower Ave. Street Address Line 1

Street Address Line 2 <blank>

City/Town Superior

State Wisconsin

Web Address

ZIP/Postal Code

<blank>

**Email Address** <blank>

## **Tobacco Product Manufacturer Information**

54880

### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco product?

How long has the person been using this type of tobacco product?

2

Select Unit of Measure

Year(s)

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

10

Select Unit of Measure

Minute(s)

How long has the person been using this particular brand or label?

2

Select Unit of Measure

Year(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

### **Tobacco Product Parts**

### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

#### Other Tobacco Products

Tobacco Product Type Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Camel BLUE, shorts

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

Every Day

#### Additional Information

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. in October and November 2014, I had seizures while driving a 18 wheeler as I was a truck driver. After seeing a specialist doctor and running many test, the doctors could not find any logical, explanation, they advised me that the federal department of transportation will no longer allow me to operate a vehicle for hires they stripped me of my medical card and forced me into a early retirement by way of disability.

### **Attached Files**

None



#### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-29

FDA ICSR ID b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

Create a name to help you find this report in the future

(max length: 50 characters)

Voluntary

**Regulatory Status** Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

### **Contact Information - Sender**

**Organization Name** <blank> Confirm Email First Name Last Name Did you report the problem No to the manufacturer? Job Title Phone Email (If prefilled, changing this email address will not change your Login email ID) Country **United States** Street Address Line 1 <blank> Street Address Line 2 <blank> City/Town State ZIP/Postal Code Sender Category Healthcare Professional (FdaTPR) Healthcare Professional type Nurse Are you the person who experienced health No problems associated with a tobacco product? Describe your relationship to the person who experienced the health problem

## **Problem Summary**

Problem Start Date

04/26/2019

#### **Problem End Date**

#### 04/26/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information. 4/29/19 0858 Student came to clinic stating she is lightheaded/dizzy and requested to lay on cot. 0900 Tonic clonic seizure began, student rolled off of back cot and onto the floor. Student had hair wrapped around face and glasses gripped tightly in hand. Student was very rigid, then began tonic clonic movements. Possible bump to head during fall. Turned to side, hair cleared from face, saliva noted coming from mouth, pillow placed under head, cot pushed out of the way. Seizure stopped at 0901, lasting 1 minute. Vitals/assessment immediately after seizure - HR: 71, SPO2: 95%, lungs clear, radial pulse strong, PERRLA. EMS called. At 0905, student was responsive with a groan. Could not follow commands or give verbal response, 0907 BG; 95, SPO2 began to fall, first to 86%, then to 78%. Oxygen mask placed on student with 1L oxygen (student pushed away nasal cannula). SPO2 rose back to 98%. EMS arrived around 0915, BP:165/90, HR:123. Student transported to Cardinal Glennon hospital around 0925. Per student, she was released later that day after MRI's and several tests. Toxicology screen was clean, doctors unsure of the cause of this seizure. This is student's second seizure. Student states that she had 3-4 hits of a friend's ecigarette that morning before school (school starts at 0725). Student states she also vaped in her car the morning of her first seizure on March 1, 2019. The first seizure occurred 0713 in the student's car in the school parking lot. After the first seizure, student spent a night in the hospital and was diagnosed with serotonin syndrome related to zoloft (one dose taken HS, and an additional dose accidentally taken in AM due to forgetfulness) in combination with Nyquil/Dayquil daily for a week or two. Second seizure was not related to serotonin syndrome.

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

Hospitalization (overnight or longer), Other serious medical event

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Per student, she was released later that day after MRIs and several tests. Toxicology screen was clean, doctors unsure of the cause of this seizure.

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

Н

Select Unit of Time

minute(s)

What is the current status of the health problem?

Recovered or Resolved

#### Affected Person

Affected Person Identifier

Code

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Female

Pregnant

No

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

17

Select Unit of Age

year(s)

Please list any known preexisting health problems for PTSD, Anxiety, Depression the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Zoloft

# What are the main symptoms or health problems?

Term describing the health problem

Tonic-clonic seizures

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

Other

Describe other electronic cigarette, electronic nicotine or vaping product subtype

Unknown. Student borrowed e-cig from a friend

Select all that apply to the electronic cigarette, electronic nicotine or vaping <blank> product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

unknown

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for

example, SKU, item/catalog number, manufacturing date/

Student borrowed from a friend - unknown

batch code)

What is the country of manufacture of the tobacco

<blank>

product?

Where is the tobacco product now?

<blank>

How was this product

acquired?

From a Friend

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

Manufacturer Investigation Information

**Tobacco Product Purchase Location** 

**Tobacco Product Manufacturer Information** 

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Some Days

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

<blank>

Select Unit of Measure

Month(s)

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

2

Select Unit of Measure

Hour(s)

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Unknown

Did this same or similar problem happen again after repeat use of the tobacco product?

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

### **Tobacco Product Parts**

#### Other Products Used

Has the affected person
used other tobacco products
(either currently or in the
past)?

#### Other Tobacco Products

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. The student states she used to use a vape pen/e-cigarette every 3 hours and was addicted for months and did not have any seizures. Months after she stopped (when parents took it away earlier in the school year) she occasionally would share a friend's vape pen and take a few hits. Twice after these occasions, she had a seizure within minutes to hours.

### **Attached Files**

None

#### MedWatch 3500B Consumer/Patient Report

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

FDA Safety Report ID #		DA Received Date	26-Apr-2019	
SECTION A - ABOUT THE PROBLEM				
		t or had a bad side effect new or worsening s)	Yes	
A1. What kind of problem was it?		roduct incorrectly which re or led to a problem		
Account of the Control of the Contro	Noticed a the produ	problem with the quality of		
		lems after switching from uct maker to another maker	Yes	
	Hospitalia longer	ration - admitted or stayed	Yes	
A1. What kind of problem was it?  A2. Did any of the following happen?	Required harm	help to prevent permanent		
	Disability	or health problem		
A2. Did any of the following happen?	Birth defe	ect		
	Life-threa	tening		-
	Death (in	clude date)		
		ious/important medical (please describe)	Yes	Seizures. 2
A3. Date the problem occurred:	25-Apr-20	19		0

I. Tell us what happened an	how it happened:
	rmy 29 year old the first took place in August of 2016 both occurred at approximately 10:30 pm activity that preceded each episode was vaping ExCigs. Both times rushed to hospital ER fler barrage of tests were low potassium level He is addicted to this vapor and both times occurred after not vaping for a day.

CTU No.: FDA-CDER-CTU-2019- (6) (6) Department: CTP | RCT No.: RCT-(6) (6) CTU Triage Date: 27-04-2019 | Total Pages: 10

A5. Relevant Tests/Laboratory Data:		
Test 1		
Test Date:	25-Apr-2019	
	CATScan	
Test Name:		
rest Name.		
	Negative	
Test Result:		
Tool House.		
2.2		
Test Unit;		
Low Test Range:		
High Test Range:		
Test 2		
Test Date:		
Test Name:		
1,000,1100,1100		
Test Result:		
7. 201.2		
Test Unit:		
Low Test Range:		
High Test Range:		
Test 3	- V	
Test Date:		
Test Name:		
N. Shrang		
7.5		
Test Result:		
Test Unit:		
Low Test Range:		
High Test Range:		
Test 4 Test Date:		
Test Date.		
Test Name:		
Test Result:		
Test Unit:		
Low Test Range:		
High Test Range:		
riigii root rango.		

CTU No.: FDA-CDER-CTU-2019 Department: CTP | RCT No.: RCT (6) (6) | CTU Triage Date 27-04-2019 | Total Pages 10

A5. Relevant Tests/Laboratory Data:		
Test 5		
Test Date:		
Test Name:		
Test (value,		
	1	
Test Result:		
- 200		
Test Unit:		
Low Test Range:		
High Test Range:		
Test 6		
Test Date:		
Tool Bolly.		
<u>_</u>		
Test Name:		
Test Result:		
rost result.		
Test Unit:		
Low Test Range:		
High Test Range:		
Test 7		
Test Date:		
Test Name:		
AC		
Test Result:		
Test Unit:		
Low Test Range:		
High Test Range:		-
Test 8		
Test Date:		
*		
Test Name:		
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Test Result:		
Test Unit.		
Low Test Range:		
High Test Range:		
TOWN TANK DISTURNS		

A5. Additional Comments:			
Many tests were taken both ER visits we have all results.			
Please select the cause of the problem that	Problem with a product		
Please select the cause of the problem that applies below:	Problem with a product Problem with a device	Yes	
		Yes	

B2. Do you have a picture of the product?

SECTION C - ABOUT THE PRODUCTS		
Product 1		
C1. This report is about	Drug	
	Cosmetic, Dietary Supplement or Food/Medical Food	
C2. Name(s) of the product as it appears on the box, bottle, or package:		
C3. Check if therapy is on-going		
C4. Name(s) of the company that makes (or compounds) the product:		
	OTC (Over-the-counter)	4
CE Deaduck Town	Compounded	
C5. Product Type:	Generic	
	Biosimilar	
C6. Expiration date:		À
C7. Lot number.		
C8. NDC number.		
C9. Strength:		
C10. Quantity:		
C11. Frequency:		
C12. How was it taken or used?		
C13a. Date the person first started taking or using the product:		
C13b. Date the person stopped taking or using the product:	84	
C14. Give best estimate of duration:		
C15. Why was the person using the product?		
C16. Did the problem stop after the person reduced the dose or stopped taking or using the product?		
C17. Did the problem return if the person started taking or using the product again?		

Product 2		
	Drug	
C1. This report is about	Cosmetic, Dietary Supplement or Food/Medical Food	
C2. Name(s) of the product as it appears on the box, bottle, or package:		*
C3. Check if therapy is on-going		
C4. Name(s) of the company that makes (or compounds) the product		
	OTC (Over-the-counter)	
C5 Product Type:	Compounded	= 1 =
C5. Product Type:	Generic	
	Biosimilar	
C6. Expiration date:		2
C7. Lot number:		
C8. NDC number:	1 y	V
C9. Strength:	1	
C10. Quantity:	4 5	II a
C11. Frequency:		1-
C12. How was it taken or used?	<u> </u>	
C13a. Date the person first started taking or using the product		
C13b. Date the person stopped taking or using the product		
C14. Give best estimate of duration:		
C15. Why was the person using the product?		
C16. Did the problem stop after the person reduced the dose or stopped taking or using the product?		
C17. Did the problem return if the person started taking or using the product again?		

CTU No.: FBA-CDER-CTU-2019 (6) | Department: CTP | RCT No.: RCT-(6) (6) | CTU Triage Date 27-04-2019 | Total Pages 10

SECTION D - ABOUT THE MEDICAL DEVICE			
D1. Name of medical device:	E- Gg		
D2. Name of the company that makes the medical device:			
D3. Model number:			
D4. Catalog number:			
D5. Lot number.			- 11
D6. Serial number:	- 1		
D7. UDI number:			
D8. Expiration date:			
D9. Was someone operating the medical device when the problem occurred?			
D9. If yes, who was operating it?	The person who had the problem A health professional (such as a doctor, nurse, or alde)		
	Someone else (Please explain who):		
D10, Date the implant was put in:		A	
D10. Date the implant was taken out:			
SECTION E - ABOUT THE PERSON WHO HAD THE PROBLEM	7,		
E1. Person's Initials:	MAN	346	
	Female	-1 -	
	Male	Yes	
E2. Gender:	Intersex		
	Transgender		
	Prefer not to disclose		
E3. Age:	2		
E4. Date of Birth:	(D) (G)		
E5. Weight:	180	16	
TO FALMINA.	Hispanic/Latino		
E6. Ethnicity:	Not Hispanic/Latino	Yes	= 1
	Asian		

American Indian or Alaskan Native Black or African American

Native Hawaiian or Other Pacific

Yes

White

Islander

E7. Race:

11. List all current prescription medic	ations and medical devices being used:	
2. List all over-the-counter medication	ns and any vitamins, minerals, supplements, and herbal remedies being used:	
CTION F - ABOUT THE PERSON FIL	ING OUT THIS FORM	
Last Name	O O	
First Name	101.01	

SECTION F - ABOUT THE PERSON FILLING OUT THIS F	FORM
F1. Last Name	(a) (d)
F2. First Name	DIO .
F3. Number/Street	(6) (0)
F4. City and State/Province	(b) (b)
F5. ZIP or Postal Code	O II D
F6. Country	US
F7. Telephone number	
F8. Email address	(o) (6)
F9. Today's date	26-Apr-2019
F10. Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No.
F11. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box (Confidentiality Requested):	Yes



## REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-04-29

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

## 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Organization Name <br/>

Confirm Email (b) (6)

First Name (0)(6)

Last Name (b) (6)

Job Title <br/>
<b

Phone (b) (6)

Email (If prefilled, changing this email address will not change your Login email ID)

(b) (6)

Country United States

Street Address Line 1 (b) (6)

Street Address Line 2 <blank>

City/Town (b) (6

State (b) (6)

ZIP/Postal Code (b) (6)

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that Consumer

apply)

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

Yes

## **Problem Summary**

Problem Start Date 03/05/2019

Problem End Date 03/05/2019

Please describe the health On March 5th, I prepared a bath for my toddler and myself. I was using problem or product problem. the Juul all day that day, as well as several weeks prior. As I sat in the

The Attachments page will accept uploads of any records, pictures, or other information. bath, things started to get "dreamy" which was later described to me as a symptom people feel immediately before their seizure. I didn't think anything of it and continued to proceed with bathing my child. After the dreamy feeling, I blacked out and then found myself on a stretcher in an ambulance. After the seizure, I remained in a blackout state, and faded in and out of alertness. My consciousness returned approximately at the same time I was checked into the hospital. During that time, my fiancee who was present for the seizure, said he watched me go from perfectly normal to convulsing with eyes rolled in the back of my head. His account was that I was washing our child, and without warning, I snapped my head to the side, started convulsing and rolling my eyes. He was terrified thinking I wasn't going to snap out of it and removed our daughter and myself from the tub while our nephew called for an ambulance. It was approximately 2 minutes for my seizure, and approximately 30 minutes to regain consciousness fully.

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

Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

During the ER visit, I had blood tests done, a urinalysis and a CAT scan performed. I was kept on an IV and monitored. After my discharge, I had to make another appointment for an EEG and an MRI, as well as a follow up to go over results.

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

12

Select Unit of Time

hour(s)

What is the current status of the health problem?

Unknown

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

Gender Female

Pregnant No

Race (Select all that apply) White

Not Hispanic or Latino Ethnicity

Birth date of the person who experienced the problem

Age of the person when the

problem occurred

30

Select Unit of Age

year(s)

Please list any known pre-

existing health problems for none the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

none

## What are the main symptoms or health problems?

Term describing the health problem

Convulsive seizure

## **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

<blank>

Was the e-liquid dripped on to the atomizer or heating element?

<blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL e-cig with Fruit Medley pods

When did the person purchase this product?

03/04/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

**Smokeless Tobacco Product** 

Package Type

<blank>

Total Package Size or Weight for Smokeless Tobacco Product

<blank>

Flavor of Smokeless Tobacco Product

<blank>

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

Purchase Location Name <br/>
<

Country <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

Phone <br/> <br/>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <br/>
<b

State <br/>

ZIP/Postal Code <br/>
<b

Web Address <br/>

Email Address <br/>
<br/

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Puffed (not inhaled)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

Yes

Describe what substances are being mixed with the tobacco product

prescription ADHD meds

Did the problem occur with first time use of the tobacco product?

No.

How long has the person been using this type of tobacco product?

2

Select Unit of Measure

Month(s)

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

5

Select Unit of Measure

Minute(s)

How long has the person been using this particular brand or label?

2

Select Unit of Measure

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

Did the person change the product in any way

No

before using it (for example, removing a filter from a cigarette)?

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

#### Other Tobacco Products

Cigarette **Tobacco Product Type** 

Full Tobacco Product Name including Brand and Sub-Marlboro lights Brand (if unknown, please enter "unknown")

Is the tobacco product Yes currently being used?

How is the tobacco product

used?

On average, how often is the tobacco product used?

<blank>

Some Days

#### **Additional Information**

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

Manufacturing as well as undisclosed chemicals/ingredients

problem. Attachments may be added on the next page.

## **Attached Files**

FILENAME IMG\_3586.jpg

Description of Attachment Statement for medical bills accumulated on 3/05

Attachment Type Photograph/Digital Image

FILENAME IMG\_3587.jpg

Description of Attachment Follow up paperwork after seizure incident

Attachment Type Photograph/Digital Image



#### REPORT INFORMATION

#### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-30

FDA ICSR ID b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## Report Identifying Information

Create a name to help you find this report in the future

(b) (6)

(max length: 50 characters)

Voluntary

**Regulatory Status** Type of Submission

Initial

What type of report are you

submitting?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

## Contact Information - Sender

Organization Name	   
Confirm Email	(b) (6)
First Name	(E) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	        
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer, Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	My daughter

## **Problem Summary**

Product Problem Type (select all that apply)

Other

Describe the other product problem

<blank>

In what setting(s) did this problem occur? (select all that apply)

Public outdoor location (park, stadium, hiking trail)

**Problem Start Date** 

02/01/2019

Problem End Date

02/01/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information. My niece, daughter and I were headed out for a show at Aura at local venue. She uses the Juul and had used it prior to arriving at the show. My niece had a vape pen with marijuana liquid in it. My daughter took one puff of it at the show and within two minutes appeared to be passing out. We held her up while she was in and out of consciousness and then she had what appeared to be a seizure. Her body went stiff, her eyes were open but was veering into the air and was not able to respond. We carried her to the door while she was stiff and unresponsive. It was the scariest moment of my life. An ambulance was called and went to the emergency room where they could find nothing and summed it up as a panic attack. I'm her mom and I know what I saw. It was a seizure. I'm grateful to have seen this article on the Today's Show website and have forwarded it to her. We have had even neurological testing done to which they found nothing.

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

Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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

15

Select Unit of Time

minute(s)

What is the current status of the health problem?

Unknown

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each

affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Female

Pregnant No.

Race (Select all that apply) Black or African American, White

Ethnicity <br/>
<b

Birth date of the person who experienced the problem



Age of the person when the

problem occurred

21

Select Unit of Age year(s)

Please list any known preexisting health problems for

the affected person

No pre existing health problems.

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

None at that time.

## What are the main symptoms or health problems?

Term describing the health problem

Unconsciousness

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping waterpipe)

Disposable (non-refillable) product, Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Uses refillable cartridge, product (including electronic cart, cartomizers or carto (that are filled by the user)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Other

Describe other e-liquid ingredients

Marijuana

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Uses juul and vaping marijuana

When did the person purchase this product?

01/30/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

No

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco United States

product?

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

Other

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

## **Tobacco Product Purchase Location**

**Purchase Location Name** Friendly Discount

Country United States

Phone (207) 747-5754

Street Address Line 1 1037 Forest Ave.

Street Address Line 2 <blank>

City/Town Portland

State Maine

ZIP/Postal Code 04103

Web Address https://friendlydiscountportland.com

**Email Address** <blank>

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) Juul

Country United States

Phone <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

<blank> State

ZIP/Postal Code <blank>

Web Address <blank>

**Email Address** <blank>

#### Tobacco Product Use Details

How was the tobacco

product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

<blank>

Are other substances being mixed in with the tobacco

product when used?

Yes

Describe what substances are being mixed with the

tobacco product

She also vaped from a pen with marijuana after using the Juul.

Did the problem occur with first time use of the tobacco

product?

How long has the person been using this type of tobacco product?

Select Unit of Measure

Year(s)

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

20

Select Unit of Measure Minute(s)

How long has the person been using this particular brand or label?

1

Select Unit of Measure Year(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

**Tobacco Product Parts** 

Other Products Used

**Other Tobacco Products** 

**Additional Information** 

**Attached Files** 

None



#### REPORT INFORMATION

#### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-04-30

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## 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 Problem associated with a tobacco product (not associated with a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> Confirm Email First Name Last Name Did you report the problem No to the manufacturer? Job Title <blank> Phone Email (If prefilled, changing this email address will not change your Login email ID) **United States** Country Street Address Line 1 Street Address Line 2 <blank> City/Town State ZIP/Postal Code Sender Category Healthcare Professional (FdaTPR) Healthcare Professional type Physician Are you the person who experienced health No problems associated with a tobacco product? Describe your relationship to the person who Physician experienced the health

## **Problem Summary**

problem

Problem Start Date 03/09/2019

**Problem End Date** 

03/09/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Grand mal seizure after use of a vape.

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

Other serious medical event

or more)

Treatment Received (select all that apply)

Emergency Room Visit Without Hospital Admission

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)

What is the current status of the health problem?

Recovered or Resolved

#### Affected Person

Affected Person Identifier Code

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Male

Race (Select all that apply) White

**Ethnicity** Unknown

Birth date of the person who experienced the problem



Age of the person when the

problem occurred

17

Select Unit of Age

year(s)

Please list any known preexisting health problems for ADHD the affected person

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Wellbutrin XL Intuniv

## What are the main symptoms or health problems?

Term describing the health problem

Seizure grand mal

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

<blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Unknown

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

Unknown

How was this product acquired?

Online Order

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

Manufacturer Investigation Information

**Tobacco Product Purchase Location** 

**Tobacco Product Manufacturer Information** 

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Some Days

Are other substances being mixed in with the tobacco product when used?

Unknown

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

<blank>

Select Unit of Measure

<blank>

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

10

Select Unit of Measure

Hour(s)

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

No

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

#### **Tobacco Product Parts**

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

**Attached Files** 

None



#### REPORT INFORMATION

#### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-05-06

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## Report Identifying Information

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

(b) (6)

(max length: 50 characters)

Voluntary

Type of Submission

**Regulatory Status** 

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank>

Confirm Email

First Name

Last Name

Did you report the problem No to the manufacturer?

<blank> Job Title

Phone

Email (If prefilled, changing this email address will not change your Login email ID)

Country United States

Street Address Line 1

Street Address Line 2 <blank>

City/Town

State

ZIP/Postal Code

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that Consumer, Concerned citizen

apply)

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

## **Problem Summary**

**Problem Start Date** 05/04/2019

**Problem End Date** 05/04/2019

Please describe the health

I experienced a minor seizure (first of my life) shortly after I started

problem or product problem. using a saltnic style vape

The Attachments page will accept uploads of any records, pictures, or other information.

Do any of these apply to the health problem? (Select one None of the above or more)

Treatment Received (select all that apply)

<blank>

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

<blank>

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

Unknown

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

Gender

Male

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

25

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

Lower back injury

### **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Norco 10/325

## What are the main symptoms or health problems?

Term describing the health problem

Partial seizures, simple

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette,

Purchased for use in a capsule, tank or refillable cartridge

electronic nicotine or vaping product

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Glycerin, Propylene Glycol

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit, Combination/mixture of flavors

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

SaltNKD 100 "Lava Flow" used with a Suorin Air

When did the person purchase this product?

05/03/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

What is the country of manufacture of the tobacco product?

United States

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

batch code)

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

## **Tobacco Product Purchase Location**

Purchase Location Name Aardvark Glass

Country United States

Phone <br/>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town Norfolk

State Virginia

ZIP/Postal Code <br/>
<b

Web Address <br/>

Email Address <br/>
<br/

## **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

3

Select Unit of Measure

Day(s)

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

90

Select Unit of Measure

Second(s)

How long has the person been using this particular brand or label?

3

Select Unit of Measure

Day(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

### **Tobacco Product Parts**

## **Other Products Used**

Has the affected person used other tobacco products Yes (either currently or in the past)?

## **Other Tobacco Products**

Tobacco Product Type Cigarette

Tobacco Product Subtype <br/>

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Marlboro Reds

Is the tobacco product currently being used?

No

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

I started vomiting after the seizure

## **Attached Files**

None

CTU No.: FDA-CDER-CTU-2019-(6) (6) Department: CTP | RCT No.: RCT-(6) (6) CTU Triage Date: 05-05-2019 | Total Pages: 6

Basic Deta	2.003/7			Tarasa	
Company l		CDER-CTU	Originating Account	FAERS	
Source Me	dium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority		Routine			
Override A	uto Calculation Rule	No			
FDA Recei	ived Date	05-May-2019	CTU Received Date	05-May-2019	
CTU Triage	e Date		CTU Data Entry Date		
Report Typ	oe .	Spontaneous	Report Classification	Drug	
Assign To		User			
User/Group	p				
Forward to	Department	CDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priori	ity	Direct			
Case Reporter	First Name	Last Name	Email Address	Phone (b) (6)	
ΔI		C-/ L-V	(SANC)		
Date the	e problem occurred		he quality of the product ching from one product maker to another make	er	
Serious	0.00.00.00.00.00.00.00.00.00.00.00.00.0	Yes			
	of the following happen? all that apply)	Hospitalization - admitte Required help to preven Disability or health probl Birth defect Life-threatening Death	t permanent harm em		
	what happened and how onal documents if nece	v it happened (Includ	medical incident(Please Describe Below) le as many details as possible F	DA may reach out to you fo	
finished but my : the sink	I cleaned up a little and I sister was right next to me	came back in the house she thought I was goir ed ghost white, my whol	Daniel's and coke a cola. I was smok grabbed some food to eat in the kito ng to throw up in the sink. Because I e body shook. My family called 911 a vape that caused this.	hen. At this point I passed out started shaking. I hit my chin on	
Relevant T	Test/Laboratory Data			1 of 1	

levant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	
More Information Available?		

Receipt No: RCT-101 (6)
CTU No: FDA-CDER-CTU-2019 Department: CTP | RCT No: RCT-101 (6) | CTU Triage Date: 05-05-2019 | Total Pages: 6

ditional Comments:				
etion B - Product Availability				
Do you still have the product in				
case we need to evaluate it?	Yes			
Do you have a picture of the product? (check yes if you are including a picture)	Yes			
ction C – About the Product				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Drug			
Name of the product as it appears on the box, bottle, or package (include as many names as you see)	The pancake house	9		
Name of the company that makes (or compounds) the product	GHOST			
Product Type (check all that apply)	Over-the-Counter Compounded by a F Generic Biosimilar	harmacy or an Outsourcing Facility		
Strength		If Other		
NDC Number				
Did the problem stop after the person reduced the dose of stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?	÷			
ıg Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form	ii			
Quantity	11	If Other		
Frequency		If Other	* 11	
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product	01-Nov-2018		*	
Date the person stopped taking or using the product	23-Apr-2019			
Give best estimate of duration				

Receipt No: RCT 1016 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019 (5) | Department, CTP | RCT No.: RCT- (6) (7) | CTU Triage Date: 05-05-2019 | Total Pages:

Is therapy still on-going?		Ш
Why was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
Returned to Manufacturer On		
Section D – About the Medical De	vice	
Name of medical device		
Name of the company that makes the medical device		
1 (400-1000) (400-100-100-100-100-100-100-100-100-100-	e model, catalog, serial, or UDI number, and the expiration date, if you can	
locate them)	s model, catalog, serial, or oblititumber, and the expitation date, it you can	
		П
Model Number		П
Catalog Number		
Lot Number		71
Serial Number		
UDDI Number		
Expiration date		
Was someone operating the		
medical device when the problem occurred?		
For implanted medical devices ON	NLY (such as pacemakers, breast implants, etc.)	
	Date the implant was taken out (If	
Date the implant was put in	relevant)	
Section E – About the Person Wh	o Had the Problem	
Person's Initials	And I	
Gender	Female	
Age (specify unit of time for age)	26 Year(s)	
Date of Birth		
Weight	65.25 kg	Ţ
Ethnicity(Choose one)	Hispanic/Latino	П
Race (Check all that apply)	American Indian or Alaskan Native	
	Native Hawaiian or Other Pacific Islander	
	Asian	
	White	
	Black or African American	Ц

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

Receipt No: RCT (6) (6) FDA 3500B Form CTU No.: FDA-CDER-CTU-2019 | Department: CTP | RCT No.: RCT-10 | CTU Triage Date: 05-05-2019 | Total Pages: Anemia Please list all allergies (such as to drugs, foods, pollen or others) N/A List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. N/A List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. N/A

tion F - About the Persor	n Filling Out This Form	1 of 1
rimary?	Yes	
Reporter is Patient?		
itle		
ast name	(b) (6)	
/liddle Name		
irst name	(b) (b)	
lumber/Street	(b) (6)	
City	(b) (6)	
State/Province	DIP (	
Country	USA	
IP or Postal code	(b) (6)	
elephone number	(b) (6)	
mail address	(b) (6)	
ax		
Reporter Organization		
epartment		
Reporter Speciality		

Generated by: SYSTEM Generated on: 05-May-2019 01:46:09 Page 4 of 5 Receipt No: RCT (6) (6)

CTU No: FDA:CDER-CTU-2019(6) (6) | Department: CTP | RCT No: RCT-(6) (6) | CTU Triage Date: 05-05-2019 | Total Pages:

Today's date 05-May-2019

Did you report this problem to the company that makes the product (the manufacturer/compounder)?

If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):

Generated by: SYSTEM Generated on: 05-May-2019 01:46:09 Page 5 of 5





#### MedWatch 3500B Consumer/Patient Report

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

FDA Safety Report ID #	(in (c)	FDA Received Date	06-May-2019	
SECTION A - ABOUT THE PROB	EM	A		
ZONON ADDOL METHOD		Were hurt or had a bad side effect (including new or worsening symptoms)	Yes	
A1. What kind of problem was it?	c .	Used a product incorrectly which could have or led to a problem		
		Noticed a problem with the quality of the product		
		Had problems after switching from one product maker to another maker		
		Hospitalization - admitted or stayed longer	Yes	
		Required help to prevent permanent harm		
		Disability or health problem		
A2. Did any of the following happ	en?	Birth defect		
		Life-threatening	Yes	
		Death (include date)		
		Other serious/important medical incidents (please describe)		
A3. Date the problem occurred:		05-May-2019		

CTU No.: FDA-CDER-CTU-2019 Department: CTP | RCT No.: RCT-(b) (6) | CTU Triage Date: 07-05-2019 | Total Pages: 10

A5. Relevant Tests/Laboratory Data:	
Test 1	
Test Date:	
Test Name:	
Test iyame,	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test2	
Test Date:	
2.00	
Test Name:	
Test Result:	
Tool (Nood).	
2-11-2	
Test Unit:	
Low Test Range:	
High Test Range:	
Test3	
Test Date;	
Test Name:	
7.17	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 4	
Test Date:	
Test Name:	
Alleria.	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Leading	1-

CTU No.: FDA-CDER-CTU-2019 | Department: CTP | RCT No.: RCT-(b) (5) | CTU Triage Date: 07-05-2019 | Total Pages 10

Test Name:  Test Name:  Test Name:  Test Result:  Test Angue High Test Rangue Test 8  Test Name:  Test Name:  Test Rangue Test 8  Test Name:  Test Rangue Test 9  Test Rangue Test 9  Test Rangue Test 7  Test Dane:  Test Rangue Test 9  Test Rangue Test 9  Test Name:	A5. Relevant Tests/Laboratory Data:		
Toest Name:  Toest			
Test Unit  Test Unit  Test Serge  Fight Test Renge  Test Serge  Test Serge  Test Result  Test Name  Test Renge  Test Y  Test Dake  Test Name  T	Test Date:		
Test Unit  Test Unit  Test Serge  Fight Test Renge  Test Serge  Test Serge  Test Result  Test Name  Test Renge  Test Y  Test Dake  Test Name  T			
Test Unit  Test Unit  Test Serge  Fight Test Renge  Test Serge  Test Serge  Test Result  Test Name  Test Renge  Test Y  Test Dake  Test Name  T	Tast Nama		
Toest Vinit  Low Teet Range  High Teet Range  Toest Name  Toest Result  Toest Range	Toot (admo.		
Toest Vinit  Low Teet Range  High Teet Range  Toest Name  Toest Result  Toest Range			
Toest Vinit  Low Teet Range  High Teet Range  Toest Name  Toest Result  Toest Range			
Toest Vinit  Low Teet Range  High Teet Range  Toest Name  Toest Result  Toest Range	Test Result:		
Low Test Range High Test Range Test Date  Test Name:  Test Name:  Test Unit Low Test Range High Test Range Test Date:  Test Name:			
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Test Name:  Test Name:  Test Name:  Test Unit: Low Test Range High Test Range  Test Date:  Test Name:			
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Test Unit Low Test Range High Test Range Test 7  Test Date:  Test Name:  Test Result:  Test Range: High Test Range:			
Test Unit Low Test Range High Test Range Test 7  Test Date:  Test Name:  Test Result:  Test Range: High Test Range:	Test Result:		
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Low Test Range: High Test Range:  Test 8  Test Date:  Test Name:  Test Result:  Test Unit. Low Test Range:			
High Test Range:  Test 8  Test Date:  Test Name:  Test Result:  Test Unit.  Low Test Range:			
Test 8 Test Date:  Test Name:  Test Result:  Test Unit.  Low Test Range:			
Test Date:  Test Name:  Test Result:  Test Unit:  Low Test Range:			
Test Name:  Test Result:  Test Unit: Low Test Range:		T.	
Test Result:  Test Unit: Low Test Range:	Test Date.		
Test Result:  Test Unit: Low Test Range:	J. Commercial Control of the Control		
Test Unit. Low Test Range:	Test Name:		
Test Unit. Low Test Range:			
Test Unit. Low Test Range:			
Test Unit. Low Test Range:	Test Deputy		
Low Test Range:	Test Result:		
Low Test Range:			
High Test Range:			
	High Test Range:		

A5. Additional Comments:		
adverse reaction		
Please select the cause of the problem that	Problem with a product	
applies below:	Problem with a device	Yes
SECTION B - PRODUCT AVAILABILITY		
B1. Do you still have the product in case we need to evaluate it?	Yes	

B2. Do you have a picture of the product?

SECTION C - ABOUT THE PRODUCTS		
Product 1		
C1. This report is about	Drug  Cosmetic, Dietary Supplement or Food/Medical Food	
C2. Name(s) of the product as it appears on the box, bottle, or package:		
C3. Check if therapy is on-going		
C4. Name(s) of the company that makes (or compounds) the product:		
	OTC (Over-the-counter)	
C5. Product Type:	Compounded	
Co. Floudet Type.	Generic	
	Biosimilar	
C6. Expiration date:	- 1 -	A
C7. Lot number:		
C8. NDC number.		
C9. Strength:		Tall:
C10. Quantity:		
C11. Frequency:		
C12. How was it taken or used?		
C13a. Date the person first started taking or using the product:	11	
C13b. Date the person stopped taking or using the product:	84	
C14. Give best estimate of duration:		
C15. Why was the person using the product?		
C16. Did the problem stop after the person reduced the dose or stopped taking or using the product?		
C17. Did the problem return if the person started taking or using the product again?		

Product 2		
1 Todate 2	Drug	T
C1. This report is about	Cosmetic, Dietary Supplement or Food/Medical Food	
C2. Name(s) of the product as it appears on the box, bottle, or package:		
C3. Check if therapy is on-going		
C4. Name(s) of the company that makes (or compounds) the product		
	OTC (Over-the-counter)	
C5. Product Type:	Compounded	
co. Froduct type.	Generic	
	Biosimilar	
C6. Expiration date:		
C7. Lot number:		
C8. NDC number:	1 y	V
C9. Strength:	1	
C10. Quantity:		
C11. Frequency:		1
C12. How was it taken or used?		
C13a. Date the person first started taking or using the product		
C13b. Date the person stopped taking or using the product		
C14. Give best estimate of duration:	1	
C15. Why was the person using the product?		
C16. Did the problem stop after the person reduced the dose or stopped taking or using the product?		
C17. Did the problem return if the person started taking or using the product again?		

CTU No.: FDA-CDER-CTU-2019 | Department: CTP | RCT No.: RCT | CTU Triage Date: 07-05-2019 | Total Pages 10

SECTION D - ABOUT THE MEDICAL DEVICE			
D1. Name of medical device:	Sourin air is the device and Liquid was juice rollup		
D2. Name of the company that makes the medical device:	Sourin USA		
D3. Model number:			
D4. Catalog number:			
D5. Lot number.		10	
D6. Serial number:			
D7. UDI number:			
D8. Expiration date:			
D9. Was someone operating the medical device when the problem occurred?	Yes		
	The person who had the problem Yes		
D9. If yes, who was operating it?	A health professional (such as a doctor, nurse, or alde)		
	Someone else (Please explain who):		
D10. Date the implant was put in:			
D10. Date the implant was taken out:			

E1. Person's Initials:	APS		
E2, Gender:	Female		
	Male	Yes	
	Intersex		
	Transgender		
	Prefer not to disclose		
E3. Age:			
E4. Date of Birth:	(0) (0)		
E5. Weight:	4		
E6. Ethnicity:	Hispanic/Latino	Yes	
	Not Hispanic/Latino		
E7. Race:	Asian		
	American Indian or Alaskan Native		
	Black or African American		
	White	Yes	
	Native Hawaiian or Other Pacific Islander	1	

Lo. List Known incurcus conditions.	
None	
E9. Please list all allergies:	
None	
E10. List any other important information about the person:	
wasasmoker	

11. List all current prescrip	iption medications and medical devices being used:	
none		
12 Liet all over the counte	ter medications and any vitamins, minerals, supplements, and herbal remedies being used:	
protein shakes	or inequations and any maining, minerals, supplements, and nerval remedies being used.	
protett attunes		

SECTION F - ABOUT THE PERSON FILLING OUT THIS I	FORM
F1. Last Name	0) (0)
F2. First Name	
F3. Number/Street	(5) (f)
F4. City and State/Province	(b) (d)
F5. ZIP or Postal Code	( <mark>575</mark>
F6. Country	
F7. Telephone number	(5) (6)
F8. Email address	(0) (6)
F9. Today's date	06-May-2019
F10. Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No.
F11. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box (Confidentiality Requested):	No



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-05-13

FDA ICSR ID b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

Create a name to help you find this report in the future

(max length: 50 characters)

Voluntary

**Regulatory Status** Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

## **Contact Information - Sender**

Organization Name <br/>

Confirm Email (b) (6)

First Name

Last Name (b) (6)

Did you report the problem to the manufacturer?

Job Title <br/>
<b

Phone (b) (6)

Email (If prefilled, changing this email address will not change your Login email ID)



Country United States

City/Town <br/>
State <br/>
State

ZIP/Postal Code <br/>
<b

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that Consumer, Concerned citizen

apply)

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

Yes

## **Problem Summary**

Problem Start Date 04/21/2019

Problem End Date 04/22/2019

Please describe the health I experienced two seizures less than 24 hours after heavy use of Juul problem or product problem. Mint product. I am a healthy, 32 year-old male with no serious pre-

The Attachments page will accept uploads of any records, pictures, or other information.

existing health conditions and no prior history of seizures. This was consumed along with alcohol and cocaine over an estimated 10 hour period. Alcohol was involved earlier (3 beers) from approximately 5 pm to 7 pm, before switching to rum and coke (approx 4-5 cups) from about 10 pm to 5 am. During the time that rum was consumed, I also consumed about .4 grams of cocaine and about 1 Mint Juul cartridge. This was all done in my private home with about 6 others present, with 3 of them consuming similar quantities of alcohol and cocaine. Only one other friend smoked the Juul device with me, but not in the same quantity. I went to sleep with my wife at around 6:30 am and woke up at around 9 am. I woke with traditional hangover symptoms (headache, thirst/dehydration, light sensitivity). My wife and I went out for lunch at a restaurant and I ate a small amount of stew and juice. My headache persisted even after we left and went back home. As soon as I arrived home. I went to use the bathroom and it was there that I suffered my first seizure at approximately 2 pm. I woke up disoriented in my bathroom with paramedics helping me. My wife called them after she heard a loud noise in the bathroom and came in to see me convulsing; foaming and bleeding from my mouth. After regaining consciousness and getting back to my feet, my wife drove me to the hospital. Once in the emergency room a nurse was taking my blood pressure and I suffered a second seizure. I was hospitalized from that point on. Spinal tap, CT Scan, EEG showed no evidence of disease, infection or other harmful medical issues. Physicians hypothesize that alcohol and drugs may have caused the seizures, but, at the time, I did not recall using the Juul device so this was not taken into consideration. However, I have evidence of purchasing Juul pods the evening prior to suffering my seizures and several witnesses that confirmed I was using it that night. I am reaching out because I researched several articles that documented a potential link between seizures and Juul devices, specifically. I would like to find out more information about any investigations into this link that may yield an explanation for the seizures I experienced. So far, this was an isolated event and I have not experienced any further medical concerns. I have also stopped using Juul or similar e-cigarette tobacco products.

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

Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Emergency response team, Emergency Room visit, Hospitalization (4 days), pending neurological evaluation with a specialist.

How long did the health problem last (if resolved), or

(if ongoing) how long has it lasted so far?

Select Unit of Time day(s)

What is the current status of the health problem?

Unknown

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender Male

Race (Select all that apply) White

Ethnicity Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the

problem occurred

32

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

Attention Deficit Disorder

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

None

# What are the main symptoms or health problems?

Term describing the health problem

Seizures

# What are the main symptoms or health problems?

Term describing the health problem

Migraine type headaches

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

electronic nicotine or vaping Uses prefilled cartridge, cart, cartomizers or carto.

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Mint (such as wintergreen or spearmint)

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

04/21/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco

**United States** 

product?

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

Manufacturer Investigation Information

## **Tobacco Product Purchase Location**

Purchase Location Name Quick Trip

Country United States

Phone <br/>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <br/> <blank>

State Georgia

ZIP/Postal Code 30080

Web Address <br/>

Email Address <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

#### **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used? Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Are other substances being mixed in with the tobacco No

product when used?

Describe what substances are being mixed with the

tobacco product

<blank>

Did the problem occur with first time use of the tobacco No

product?

How long has the person been using this type of tobacco product?

7

Select Unit of Measure Month(s)

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

Select Unit of Measure Month(s)

How long has the person been using this particular brand or label?

7

Select Unit of Measure Month(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

## **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

## Other Tobacco Products

**Tobacco Product Type** Cigarette Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

No

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

## **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-05-14

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	   
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (8)
Did you report the problem to the manufacturer?	No
Job Title	        
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Consumer, Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Father

# **Problem Summary**

**Problem Start Date** 

05/02/2019

Problem End Date

05/02/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Son admitted to using Juul Vape Device and within 15 Minutes had a seizure reportedly for 5-8 minutes. Ambulance Called and transported to Emergency Room, full work up including ped-neuro at SUNY Upstate with no findings. No additional seizures since.

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

Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Ambulance, Emergency Room full work up, labs, EKG, Head CT, EEG, Brain MRI, Lyme Test and Fasting Blood Glucose.

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

Select Unit of Time day(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

1

Gender

Male

Race (Select all that apply)

White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

17

Select Unit of Age year(s)

Please list any known preexisting health problems for the affected person

No previous health issues or seizures.

# **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Multi Vitamin.

# What are the main symptoms or health problems?

Term describing the health problem

Seizure

## **Tobacco Products**

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal

vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or

carto.

product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

05//2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product acquired?

<blank>

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

Purchase Location Name Fast Track

Country United States

Phone <br/>

Street Address Line 1 Aresnal St

Street Address Line 2 <blank>

City/Town Watertown

State New York

ZIP/Postal Code 13601

Web Address <br/> <br/>

Email Address <br/>
<br/

## **Tobacco Product Manufacturer Information**

## **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	18
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the problem occur?	15
Select Unit of Measure	Minute(s)
How long has the person been using this particular brand or label?	18
Select Unit of Measure	Month(s)
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar problem happen again after repeat use of the tobacco product?	No
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	Yes
Please explain how the product was changed prior	Used a different pod.

## **Tobacco Product Parts**

to its use

**Other Products Used** 

**Other Tobacco Products** 

**Additional Information** 

**Attached Files** 

None

CTU No.: FDA-CDER-CTU-2019 | Department: CTP | RCT No.: RCT-16) (6) | CTU Triage Date: 16-05-2019 | Total Pages: 5

asic Deta	ayed in the report are in EST(GI ails				
Company l		CDER-CTU	Originating Account	FAERS	
Source Me	dium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority Override Auto Calculation Rule		Routine			
		No			
FDA Recei	eived Date	16-May-2019	CTU Received Date	16-May-2019	
CTU Triage	e Date		CTU Data Entry Date		
Report Typ	e	Spontaneous	Report Classification	Drug	
Assign To		User			
User/Group	•				
Forward to	Department	CDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priori	ity	Direct			
ontact		_		-	
Case Reporter	First Name	Last Name	Email Address	Phone	
Z	(b) (b)	(b) (6)	(b) (6)	(b) (6)	
Section A	- About the Problem		1-1-1		
Date the problem occurred  Serious  Did any of the following happen? (Check all that apply)		29-Apr-2019 Yes			
		Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)			
Tell us w	what happened and how onal documents if nece	v it happened (Includ	de as many details as possible f	FDA may reach out to you fo	
Had diz seizures		pressure, paralysis cau	sing hospitalization in ICU. Since the	en, seizure type symptoms—foca	
Relevant T	Fest/Laboratory Data			1 of 1	
Test Na	ime		Test Date		
Test Re	sult	Ti.	Test Unit		
Low Test Range		High Test Range			
	formation Available?		In Management		
wore information Available?					

Receipt No: RCT-10116 FDA 3500B Form
CTU No: FDA-CDER-CTU-2019-10300 | Department: CTP | RCT No: RCT-10116 | CTU Triage Date: 16-05-2019 | Total Pages: 5

ditional Comments				
ction B - Product Availability				
Do you still have the product in case we need to evaluate it?	Yes			
Do you have a picture of the product? (check yes if you are including a picture)	No			
ction C - About the Products			1 of	1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Drug			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Juul			
Name of the company that makes (or compounds) the product	Tobacco Company	Tobacco Company		
Product Type(check all that apply)	Over-the-Counter Compounded by a Generic Biosimilar	Compounded by a Pharmacy or an Outsourcing Facility  Generic		
Strength		If Other		
NDC number		1.3.4.1.1		
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Yes			
ig Therapy			1 of	1
Expiration date				
Lot number				
Dosage Form	ii -			
Quantity		If Other		
Frequency	1	If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product	03-Jan-2018		*	
Date the person stopped taking or using the product	16-May-2019			
Give best estimate of duration				

 Generated by:
 SYSTEM
 Generated on:
 16-May-2019 01:45:57
 Page 2 of 5

Receipt No: RCT (6) (6) FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019 CX 0 | Department: CTP | RCT No.: RCT-(b) (5) | CTU Triage Date: 16-05-2019 | Total Pages: 5

	Is therapy still on-going?	Yes	1
W	hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Quit smoking		
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
O	ther identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
E	Model Number		
T.	Catalog Number		
	Lot Number		
	Serial Number		
Ш	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fc	or implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
D	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	no Had the Problem	
	Person's Initials	(6,16)	
	Gender	Female	
	Age (specify unit of time for age)	45 Year(s)	
	Date of Birth		
i,	Weight	59.4 kg	Ţ
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	

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

FDA 3500B Form Receipt No: RCT (6) (6) CTU No.: FDA-CDER-CTU-2019-07/0 | Department: CTP | RCT No.: RCT-10 | CTU Triage Date: 16-05-2019 | Total Pages: Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices eing used. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. None Section F - About the Person Filling Out This Form 1 of 1 Primary? Yes Reporter is Patient? Title Last name (b) (6) Middle Name First name Number/Street (b) (6) (b) (6) City State/Province USA Country ZIP or Postal code Telephone number

Generated by: SYSTEM Generated on: 16-May-2019 01:45:57 Page 4 of 5

Email address

Department

Reporter Organization

Reporter Speciality

Receipt No: RCT (6) (6)

CTU No: FDA:CDER-CTU-2019 (6) | Department: CTP | RCT No: RCT-(6) (6) | CTU Triage Date: 16-05-2019 | Total Pages:

manufacturer, please mark this box (Confidentiality Requested):

Today's date

Did you report this problem to the company that makes the product (the manufacturer/compounder)?

If you do NOT want your identity disclosed to the

Generated by: SYSTEM Generated on: 16-May-2019 01:45:57 Page 5 of 5



#### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-05-22

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## 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?

a product problem or defect)

Health Problem associated with a tobacco product (not associated with

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	<blank></blank>
Confirm Email	(b) (6)
First Name	1000
Last Name	(6) (6)
Did you report the problem to the manufacturer?	No
Job Title	   
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Sister

# **Problem Summary**

**Problem Start Date** 

12/14/2018

Problem End Date

05/22/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

My sister is a college athlete, perfectly healthy her entire life, and started having seizures after recently beginning to Juul socially. She has now been diagnozed with Juvenile Myoclonic Epilepsy because she has seizures so often. She has since stopped Juuling which has helped, but she still is experiencing seizures or convulsions almost daily.

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

Lasting disability or other permanent health problem, Life threatening, Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

SHe was put on anti seizure medication which has not helped much.

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Female

Pregnant

<blank>

Race (Select all that apply) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the problem occurred

22

Select Unit of Age

year(s)

Please list any known preexisting health problems for none the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

none

## What are the main symptoms or health problems?

Term describing the health problem

Seizures

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping

Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user)

product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Water

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit, Candy or Chocolate

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

12/10/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

United States

Where is the tobacco product now?

Product was discarded

How was this product acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## Manufacturer Investigation Information

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is Every Day this tobacco product used?

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco product?

How long has the person been using this type of tobacco product?

Select Unit of Measure

Month(s)

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

30

Select Unit of Measure

Minute(s)

How long has the person been using this particular brand or label?

6

Select Unit of Measure

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products No (either currently or in the past)?

#### **Other Tobacco Products**

#### Additional Information

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

It is absolutely insane that e-cigarettes are being marketed to teenagers and marketed as an alternative to smoking in general. The Juul

problem. Attachments may commerce be added on the next page. removed.

commerical, the print ads, the advertisements on the streets need to be removed.

## **Attached Files**

None



## REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-05-23

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

## 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?

Both (health problem that is also associated with a product problem or

defect)

Did you report this problem somewhere else (outside No SRP)?

# Contact Information - Sender

Organization Name	        
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	   
Job Title	   
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	       
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	My son

## **Problem Summary**

Product Problem Type (select all that apply)

Label issue

In what setting(s) did this problem occur? (select all that apply)

One person using one or more product(s), In the place where I live

**Problem Start Date** 

11//2018

Problem End Date

<blank>

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information. My son started smoking a Juul vape pen about one and a half years ago. In November he was talking to me when he passed out suddenly on our dinning room floor. He was taken to the hospital by me and was told he was probably dehydrated. Then on April 24, 2019 he was taken by ambulance to the hospital because of not wanting to get out of bed and being confused. While at the hospital he took a hit off of his Juul vape and within 3-5 minutes he had a violent Grand Mal Seizure which resulted him being intubated and put on a breath ventilator for the next 12 hours. He spent 5 days in the hospital and during that time, several test were done and nothing has shown up as to why he had this seizure. His kidneys were only working 30% so he hasn't been released by his kidney doctor. Until he's cleared by that doctor he can't have an MRI with contrast, however the neurologists doesn't think they will see anything. Right now all indications are pointing to a nicotine overdose from using the Juul vape. I firmly believe this is this case. I don't know how to go about proving this, other than his other test are normal. I've read online up to 35 other cases where seizures were associated with Juul vapes and strongly believe this is what happened to my son. As a concerned parent, I think the labels should also read that seizures are a possibility when using these products.

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

Life threatening, Hospitalization (overnight or longer)

Reported Cause of Death

<blank>

Treatment Received (select all that apply)

<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)

What is the current status of the health problem?

Not Recovered or Unresolved

#### **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a

User(s)

separate report for each affected person, if possible.)

How many users were

affected?

1

How many nonusers were

affected?

<blank>

Gender

Male

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem

<blank>

Age of the person when the

problem occurred

22

Select Unit of Age

year(s)

Please list any known pre-

existing health problems for

the affected person

<blank>

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health

<blank>

problem.

## What are the main symptoms or health problems?

Term describing the health problem

Seizure grand mal

#### **Tobacco Products**

Any other identifying

tobacco product codes (for

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice) **Tobacco Product Subtype** Electronic cigar or e-cigar Select all that apply to the electronic cigarette, Rechargeable product, Uses prefilled cartridge, cart, cartomizers or electronic nicotine or vaping carto. product (including electronic waterpipe) Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, Purchased in a non-refillable disposable cartridge electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the Nicotine, Coloring Agents, Flavor(s), Propylene Glycol, Other following? (select all that apply) Describe other e-liquid Benzoic acid ingredients What type(s) of flavor(s) Tobacco, Menthol, Mint (such as wintergreen or spearmint), Fruit, does the e-liquid contain? Combination/mixture of flavors (select all that apply) Was the e-liquid dripped on to the atomizer or heating Unknown element? Full Tobacco Product Name. including Brand and Sub-Juul made by Juul Labs, Incorporated, Pax, Eon Pods owned by Eon Brand (if unknown, please PODS LLC. enter "unknown") When did the person //2018 purchase this product? UNIVERSAL PRODUCT <blank> CODE (UPC) from Label Does the involved product device or package bear the Don't Know "UL" symbol?

I threw all Juul related items away after his violent Grand Mal Seizure.

example, SKU, item/catalog number, manufacturing date/ batch code)

What is the country of manufacture of the tobacco

product?

**United States** 

product?

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

Purchase Location Name <br/>
<

Country <br/> <blank>

Phone <br/>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <br/> <b

State <br/>

ZIP/Postal Code <br/>
<b

Web Address <br/>

Email Address <br/>
<br/

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

2

Select Unit of Measure

Year(s)

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

3

Select Unit of Measure

Minute(s)

How long has the person been using this particular brand or label?

2

Select Unit of Measure

Year(s)

Did the person continue to use this tobacco product after the problem occurred?

No

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

## **Other Tobacco Products**

Tobacco Product Type Snus (pouches or loose)

Tobacco Product Subtype Loose snus

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Copenhagen long cut wintergreen made by U.S. Smokeless Tobacco Company

Is the tobacco product currently being used?

No

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. Juul Electronic Vape Cigarettes are dangerous in not only are they addicting, but also seizures can be a side effect. Too many young kids are addicted to using these. My son was already addicted to nicotine by using chewing tobacco. He wanted to take better care of his teeth, so he switched to the new trend of vaping the Juul, not realizing how much more nicotine is in a pod.

## **Attached Files**

juul-juul-pod-mango-4-pack-2\_grande\_aa741310-aeb3-4cbb-b5c0-b0b2529f3b03.jpg FILENAME

**Description of Attachment** 

Attachment Type Labeling Materials



## REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-05-27

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

## 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** Confirm Email First Name Last Name Did you report the problem <blank> to the manufacturer? Job Title <blank> Phone Email (If prefilled, changing this email address will not change your Login email ID) Country **United States** Street Address Line 1 Street Address Line 2 <blank> City/Town State

ZIP/Postal Code

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that

apply)

Consumer, Concerned citizen

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

## **Problem Summary**

**Problem Start Date** 01/15/2017

**Problem End Date** <blank>

Please describe the health

I had been using a vape pen in order to quit smoking. I was using a problem or product problem. medium amount of nicotine and trying to reduce the amount. I had

The Attachments page will accept uploads of any records, pictures, or other information. been using it for about two months. Around January 15, 2017 (I can get the exact date from medical records), I had my first focal seizure at age 37. I stopped using the vape and Wellbutrin, but still continued to have about one or two seizures a month until the summer of 2017. I am seeing a neurologist who has me on Lamictal. He increased the dosage from 200 to 400 over the next year. The seizures became less frequent and I am now stable since the summer of 2018.

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

Hospitalization (overnight or longer), Needed treatment to prevent permanent harm

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

After the first seizure, I was admitted ovemight to the hospital. I have had an MRI, CT, EEG, Ambulatory EEG. All these have not shown anything. My neurologist treated me with one medication that did not work (I can't remember the name) and then settled on Lamictal and kept increasing the dose after seizures and is now at 400 mg. It seems to be working and I am now stable.

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

18

Select Unit of Time

month(s)

What is the current status of the health problem?

Unknown

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Male

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

37

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

Obese, sleep apnea, depression, acid reflux

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Wellbutrin, Prevacid

## What are the main symptoms or health problems?

Term describing the health problem

Partial seizures, complex

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Button activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

unknown

When did the person purchase this product?

11//2016

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

Product was discarded

How was this product acquired?

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

Purchase Location Name Grassy Plain Vape and Smoke

Country United States

Phone (203) 917-3597

Street Address Line 1 39 Grassy Plain St

Street Address Line 2 Suite A

City/Town Bethel

State Connecticut

ZIP/Postal Code 06801

Web Address grassyplain.com

Email Address <br/>
<br/

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with	

first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

2

Select Unit of Measure Month(s)

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

12

Select Unit of Measure Hour(s)

How long has the person been using this particular brand or label?

2

Select Unit of Measure Month(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products

#### **Other Tobacco Products**

Tobacco Product Type Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

American Spirit, light green

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

inhaled (smoked or vaped)

On average, how often is the tobacco product used?

Every Day

#### Additional Information

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

#### **Attached Files**

None



#### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-05-29

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

Organization Name <br/>

Confirm Email <br/>
<br/

First Name (D) (6)

Last Name (0) (2)

Did you report the problem to the manufacturer?

Job Title <br/>
<b

Phone <br/>

Email (If prefilled, changing this email address will not change your Login email ID)

<blank>

Country <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

Street Address Line 1 <br/>
<b

Street Address Line 2 <blank>

City/Town <br/> <blank>

State <br/>

ZIP/Postal Code <br/>
<b

Sender Category Healthcare Professional (FdaTPR)

Healthcare Professional type

(b) (6)

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

No

Describe your relationship to the person who experienced the health problem

Health care provider

## **Problem Summary**

Problem Start Date

<blank>

**Problem End Date** 

<blank>

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Patient complained of three episodes of loss of consciousness and feeling "jittery" and "weak".

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

None of the above

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Patient was advised that she was most likely experiencing a vaping related seizure and nicotine toxicity as she was vaping a "pod" or more a day for approximately one to two weeks. Patient was advised to stop vaping immediately. Symptoms resolved.

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

Recovered or Resolved

## Affected Person

Affected Person Identifier Code

<blank>

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

<blank>

Gender

Female

Pregnant No

Race (Select all that apply) White

**Ethnicity** Unknown

Birth date of the person who experienced the problem

<blank>

Age of the person when the problem occurred

42

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

<blank>

# **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

<blank>

## What are the main symptoms or health problems?

Term describing the health problem

Loss of consciousness

## **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

<blank>

Full Tobacco Product Name, including Brand and Sub-

Juul with nicotine

Brand (if unknown, please enter "unknown")

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

<blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

<blank>

How was this product

<blank>

acquired?

Do you know where the

ditte to

product was purchased?

<blank>

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

**Manufacturer Investigation Information** 

**Tobacco Product Purchase Location** 

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

<blank>

On average, how often is this tobacco product used?

<blank>

Are other substances being mixed in with the tobacco product when used?

<blank>

Did the problem occur with first time use of the tobacco product?

<blank>

How long has the person been using this type of tobacco product?

<blank>

Select Unit of Measure

<blank>

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

<blank>

Select Unit of Measure

<blank>

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

<blank>

Did this same or similar problem happen again after repeat use of the tobacco product?

<blank>

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

#### **Tobacco Product Parts**

## **Other Products Used**

Has the affected person used other tobacco products (either currently or in the past)?

#### Other Tobacco Products

Tobacco Product Type Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

No

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

## **Attached Files**

None



## REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-05-31

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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



Regulatory Status Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> Confirm Email First Name Last Name Did you report the problem <blank> to the manufacturer? Job Title <blank> Phone Email (If prefilled, changing this email address will not change your Login email ID) Country **United States** Street Address Line 1 Street Address Line 2 <blank> City/Town State ZIP/Postal Code Sender Category Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Consumer apply) Are you the person who experienced health

## **Problem Summary**

problems associated with a

tobacco product?

 Problem Start Date
 05/30/2019

 Problem End Date
 05/30/2019

Please describe the health Laying down when lights really started bothering me. Got up to turn problem or product problem. brightness down on tv and collapsed. Payed down in bed for 5 minutes.

The Attachments page will accept uploads of any records, pictures, or other information. Tried to get up and walk and my brain felt like it was going crazy and I feel like I had my first seizure ever that lasted about 30 seconds before I snapped out of it. Heart was racing like crazy for the rest of the night everytime I tried to do anything besides sleep. Woke up feeling much better.

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

<blank>

Treatment Received (select all that apply)

None

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

3

Select Unit of Time

hour(s)

What is the current status of the health problem?

Unknown

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

4

Gender

Male

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem

(b) (6)

Age of the person when the problem occurred

24

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

None

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Vyvanse (40mg) taken 12 hours before seizure. Smoked marijuana an hour before seizure.

## What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

Tobacco Product Type

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

<blank>

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

When did the person purchase this product?

04/25/2019

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)

<blank>

What is the country of manufacture of the tobacco United States product?

Where is the tobacco product now?

User/Consumer has the product

How was this product

acquired?

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

## **Tobacco Product Purchase Location**

**Purchase Location Name** Wild side smoke shop

United States Country

Phone <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code 48324

Web Address <blank>

**Email Address** <blank>

#### **Tobacco Product Manufacturer Information**

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Some Days

Are other substances being mixed in with the tobacco product when used?

No

Did the problem occur with first time use of the tobacco product?

No

How long has the person been using this type of tobacco product?

1

Select Unit of Measure

Month(s)

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

10

Select Unit of Measure

Minute(s)

How long has the person been using this particular brand or label?

1

Select Unit of Measure

Month(s)

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

#### **Tobacco Product Parts**

Full Tobacco Product Part Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Juul

**Tobacco Product Part Type** 

Battery(reusable)

When was this tobacco product part purchased or acquired?

05/23/2019

UNIVERSAL PRODUCT

<blank>

CODE (UPC) from Label

Any other identifying

tobacco product part <br/>
<br

codes(e.g. SKU, item/catalog number)

What is the country of

manufacture of the tobacco

cco United States

product part?

Where is the tobacco product part now?

User/Consumer has the product

Do you know who manufactured this tobacco

No

product part?

## **Tobacco Product Part Purchase Location**

How was this tobacco product part acquired?

In a Store

**Purchase Location Name** 

Wild side smoke shop

Country

United States

Phone

<blank>

Street Address Line 1

<blank>

Street Address Line 2

<blank>

City/Town

<blank>

State <br/>
ZIP/Postal Code <br/>
Web Address <br/>
Email Address <br/>
<br/>
State <br/>

## **Tobacco Product Part Manufacturer Information**

State <black>

State/Province <br/>
<br

#### **Other Products Used**

Has the affected person used other tobacco products Yes (either currently or in the past)?

## **Other Tobacco Products**

Tobacco Product Type Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

Marlboro, camel cigarettes

Is the tobacco product currently being used?

Yes

How is the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is the tobacco product used?

Some Days

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

# **Attached Files**

None

CTU No.: FDA-CDER-GTU-2019-10 (0) Department: CTP | RCT No.: RCT-(0) (6) | CTU Triage Date: 31-05-2019 | Total Pages:

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		1
Override Auto Calculation Rule	No		
FDA Received Date	03-Apr-2019	CTU Received Date	30-May-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		1
User/Group			
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Case Reporter	First Name	Last Name	Email Address	Phone
	(D) (Ö)	(b) (6)	(b) (6)	(b) (6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)  Used a product incorrectly which could have or led to a problem  Noticed a problem with the quality of the product	
Date the problem occurred	LI Had problems after switching from one product maker to another maker  25-Jan-2015	-
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)	Diagnosed with epilepsy	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I started having seizure like symptoms in high school and after I graduated I started to vape more frequently eventually crashing my car into possibly due to a seizure/blackout in early 2015. I went on to have seizures about every 6-8 months. My last known seizure was on 03/09/18 when I failed to take my medication for a week. I was vaping a lot during that week since it was spring break and I was free to vape more often. After that seizure I started taking my medication regularly and would have a déjà vu feeling but no blackout or seizure would occur. I stopped vaping in January 2019 and I didn't have any symptoms until I started vaping again. Symptoms I typically have include, dizziness, random feelings of déjà vu with a light feeling almost as if I'm floating, followed by an ammonia like odor just prior to having a seizure. I have been told that I let out a loud grumble/ scream seconds before I start convulsing. I have always been overweight and had higher blood pressure since childhood. Time line of important events 2011 December - Started Vaping with a pen from the gas station. 2012 May - had a possible nocturnal episode where I was in a deep sleep and was completely unresponsive. 2012 June - Had another possible seizure where I started convulsing in my sleep after a final exam. 2013 June- Started vaping more regularly with an upgraded box-mod (high volume of vapor and nicotine). 2013 - Continued to have issues where I would be unresponsive during sleep. (note that I am a heavy sleeper but this was different. My mom literally dragged me out of bed and called the paramedics several times.)

2013 into 2014 - Went to the hospital on multiple occasions for loss of memory and random lightheaded feelings. Sometime in 2014 - Drove to school up the street at around 3:30-3:45 in the afternoon; I woke up parked in a parking space 4 to 5 miles down the road with my foot on the brake around sunset. I don't remember driving past the college 2014 August - On my way to work I starting getting a déjà vu feeling, I pulled over and walked into a Foodlion, passed out, and was taken to the hospital. I could feel it coming on and wanted to get to a public area off the road. I only remember parking my car, the walk into the store was explained to me after. 2015 Late January early February - Drove my brothers friend home after dinner. I woke up in an ambulance after crashing my car into a tree in the entrance to my neighborhood. I don't remember but half of the drive home. Drivers License was suspended and I was referred to a cardiology specialist and a neurology specialist. 2015 - Did multiple tests for cardiology and neurology including prescription medications to lower heart rate and blood pressure as well as a trial with Keppra (Levetiracetam). I did a sleep study to look into the night time events. I did a tilt table test that resulted in my heart stopping after they sprayed the nitroglycerin under my tongue. We installed a loop recorder (removed in October 2018) that recorded my heart rate at any given time. Over the next few years we determined that my lower chamber was going faster than my upper chamber causing my heart rate to increase to over 170 when doing normal daily activities. I participated in a seizure study where I was monitored with an EEG and camera 24/7 for about a week, this resulted in slightly abnormal brain activity but no clear signs of seizures. 2016 November - Had a seizure in Connecticut. My cousin who is an RN for a cardiology specialist witnessed it and said that was definitely neurology related. The ER doctor prescribed Tegratol (Carbamazepine) because I had a poor reaction with Keppra. 2016 November - Had a seizure on the Jersey Turnpike as a passenger on the trip home from Connecticut. Lost my vape and stopped vaping for several months. 2017 October DMV and neuro approved my license for being seizure free. I don't know the number of seizure I've had, but more 20. Vaped on/off since 2012.

levant Test/Laboratory Data	a		1 of 5
Test Name	TILT TABLE TEST	Test Date	
Test Result	Failed, flat-lined for 15	Test Unit	SECONDS
Low Test Range		High Test Range	
More Information Available?			•
elevant Test/Laboratory Data	a		2 of 5
Test Name	SLEEP STUDY FOR SLEE P APNEA	Test Date	
Test Result	Possible mild-to-moderate sleep apnea	Test Unit	
Low Test Range		High Test Range	14 12
More Information Available?			
elevant Test/Laboratory Data	а		3 of 5
Test Name	PORTABLE EKG	Test Date	
Test Result	Normal	Test Unit	
Low Test Range		High Test Range	
More Information Available?			
elevant Test/Laboratory Data	a		4 of 5
Test Name	EEG	Test Date	
Test Result	Normal	Test Unit	
Low Test Range		High Test Range	
More Information Available?			
elevant Test/Laboratory Data	а		5 of 5
Test Name	SEIZURE STUDY IN HOS PITAL	Test Date	
Test Result	Inconclusive- some abnor mal brain activity in spec	Test Unit	

Generated by: SYSTEM Generated on: 30-May-2019 20:16:41 Page 2 of 6

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	Low Test Range	High Test Range
	More Information Available?	
Ā	dditional Comments	
	where I would pass-out and occas I do not have the specific dates of the information in front of me at th	on with cardiology and neurology to determine why I was having these seizure like episodes onally convulse. I have done multiple EEG and EKG tests and only stated one test for each, hese tests and I know that there are a few more that I haven't mentioned due to not having moment. I will be able to provide all medical records if needed. I ran out of space in he able to provide more information and examples if requested.
S	ection B - Product Availability	
1	Do you still have the product in case we need to evaluate it?	Yes
ĺ	Do you have a picture of the product? (check yes if you are including a picture)	No -
S	ection C - About the Products	1 of 1
- Contract of the Contract of	Suspect	Yes
	Primary?	Yes
T	Туре	Drug/Biologic
ī	This report is about	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Vape oil; Propylene Glycol, Vegetable Glycerin, nicotine, and flavors
	Name of the company that makes (or compounds) the product	Various companies
	Product Type(check all that apply)	Over-the-Counter  Compounded by a Pharmacy or an Outsourcing Facility  Generic  Blosimilar
Ē	Strength	If Other
F	NDC number	
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes
	Did the problem return if the person started taking or using the product again?	Yes
D	rug Therapy	1 of 1
	Expiration date	
	Lot number	
	Dosage Form	
	Quantity	If Other
	Frequency	If Other
Ī	How was it taken or used	If Other
	Date the person first started taking or using the product	31-Dec-2011

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CTU No: FDA-CDER-CTU-2019 500 | Department: CTP | RCT No: RCT-6) CTU Triage Date: 31-05-2019 | Total Pages: 6

	Date the person stopped taking or using the product	01-Jan-2019	
	Give best estimate of duration		
	Is therapy still on-going?		
W		roduct? (such as what condition was it supposed to treat) 1 of 1	
	Stop smoking tobacco		
	Returned to Manufacturer On		П
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Ot	ther identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
loc	cate them)		
	Model Number		
7-1	Catalog Number		
jii.	Lot Number		
	Serial Number		
	UDDI Number		
П	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	or implanted medical devices C	DNLY (such as pacemakers, breast implants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wr	no Had the Problem	
	Person's Initials		
	Gender	Male	
	Age (specify unit of time for age)		
	Date of Birth	(b) (6)	
	Weight	126 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaskan Native	
		American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White	

THE	
Lis	st known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
	Overweight, higher blood pressure, and Asperger's
Ple	ease list all allergies (such as to drugs, foods, pollen or others)
	None known
-	
Lis	t any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
	smoker/vaper, occasionally drinks alcohol
ne:	at all current prescription medications and medical devices being used.
-10	Carbamazepine
	Carbamazepine
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
	none

ction F - About the Persor	Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(6)	
Middle Name		
First name	(b) (d)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	B-15	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		

Receipt No: RCT-(b) (6) FDA: S00B Form
CTU No: FDA: CDER-CTU-2019 (b) (b) Department: CTP | RCT No: RCT-(b) (6) | CTU Triage Date: 31-05-2019 | Total Pages.

Department

Reporter Speciality

Today's date

Did you report this problem to the company that makes the product (the manufacturer/compounder)?

If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):

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Receipt No: RCT FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-101/01 | Department: CTP | RCT No.: RCT 15 (6) | CTU Triage Date: 31-05-2019 | Total Pages.

Company l	ails Unit	CDER-CTU	Originating Account	FAERS
Source Me		MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	-	Routine	224,227,3101,10P2	
	uto Calculation Rule	No		
FDA Recei	ved Date	03-Apr-2019	CTU Received Date	30-May-2019
CTU Triage	e Date	10.00	CTU Data Entry Date	35 425 425
Report Type		Spontaneous	Report Classification	Drug
Assign To		User	12 22 37 12 300	1 2 2 2
User/Group	)			
Forward to	Department	CDER (CDER-O	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priori	ity	Direct	2 1 0(@)444.III 0.904/ (LZD)	
Contact	State of the latest terminal	- V	The second division in	
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6) (b) (c)		(b) (b)
	- About the Problem		) •	
	nd of problem was it? all that apply)		side effect (including new or worsening sympto	ims)
(Check	all that apply)	Used a product incorrect Noticed a problem with Had problems after swit	side effect (including new or worsening sympto ctly which could have or led to a problem the quality of the product tching from one product maker to another make	
(Check	all that apply) e problem occurred	Used a product incorrect Noticed a problem with Had problems after swite O2-Jan-2019	ctly which could have or led to a problem the quality of the product	
Date the	all that apply) e problem occurred	Used a product incorrect Noticed a problem with Had problems after swit 02-Jan-2019 Yes	ctly which could have or led to a problem the quality of the product tching from one product maker to another make	
Date the Serious	all that apply) e problem occurred	Used a product incorrect Noticed a problem with Had problems after swite O2-Jan-2019  Yes  Hospitalization - admitte Required help to prever Disability or health problem Birth defect Life-threatening Death	ctly which could have or led to a problem the quality of the product tching from one product maker to another make ed or stayed longer at permanent harm	
Date the Serious Did any (Check	all that apply) e problem occurred of the following happen? all that apply)	Used a product incorrect Noticed a problem with Had problems after swite O2-Jan-2019  Yes  Hospitalization = admittee Required help to preven Disability or health problem Birth defect  Life-threatening Death Other serious/important	ctly which could have or led to a problem the quality of the product tching from one product maker to another make ed or stayed longer of permanent harm elem : medical incident(Please Describe Below)	er
Date the Serious Did any (Check	all that apply) e problem occurred of the following happen? all that apply)	Used a product incorrect Noticed a problem with Had problems after swite O2-Jan-2019  Yes  Hospitalization = admittee Required help to prever Disability or health problem Birth defect Life-threatening Death Other serious/important with appened (Include in the problem)	ctly which could have or led to a problem the quality of the product tching from one product maker to another make ed or stayed longer at permanent harm	er

elevant Test/Laboratory Data	V-10-10-10-10-10-10-10-10-10-10-10-10-10-	1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	
More Information Available?	***	

Receipt No.: RCT-101 (6)
CTU No.: FDA-CDER-CTU-2019-101-01 | Department: CTP | RCT No.: RCT-101-15 | CTU Triage Date: 31-05-2019 | Total Pages: 5 FDA 3500B Form

Additional Comments				
Section B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
Section C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Cosmetic, Dietary Supplen	nent or Food/Medicinal Food	1	
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blood Orange			
Name of the company that makes (or compounds) the product	Mr. Salt-E E-Liquid Salts			
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic Biosimilar	or an Outsourcing Facility		
Strength		If Other		
NDC number		- Landau - L		
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Yes			
Drug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form				
Quantity		If Other	-17	
Frequency		If Other		
How was it taken or used	Respiratory (inhalation)	If Other		
Date the person first started taking or using the product	01-Dec-2018		*	
Date the person stopped taking or using the product	04-Feb-2019			
Give best estimate of duration				

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Receipt No: RCT (6) (6) FDA 3500B Form

CTU No.: FDA:CDER-CTU-2019 CXXVI | Department: CTP | RCT No.: RCT-10 | CTU Triage Date: 31-05-2019 | Total Pages: 5

	Is therapy still on-going?		4
W	hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	B. 1. 1. 2. 2		
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
O	ther identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
100	cate them)		
	Kilosalal Klassafa en		
	Model Number		1
Ш	Catalog Number  Lot Number		
4	Serial Number		
	UDDI Number		
	Expiration date		2.11
	Was someone operating the medical device when the problem occurred?		
Fo	or implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
2	ection E - About the Person Wh	on Had the Problem	
	Person's Initials	io rica are i robistit	
H	Gender	Male	
	Age (specify unit of time for age)	16 Year(s)	
÷	Date of Birth	10 104(0)	
	Weight	58.5 kg	
	Ethnicity (Choose only one)	Hispanic/Latino	
	Race (Check all that apply)		
1	(Mace (Officer all that apply)	American Indian or Alaskan Native	
		Native Hawaiian or Other Pacific Islander	
		☐ Asian	
		White	
-		Black or African American	

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

Receipt No: RCT-(b) (6)

CTU No.: FDA-CDER-CTU-2019-10169 | Department: CTP | RCT No.: RCT-(b) 151 | CTU Triage Date; 31-05-2019 | Total Pages: 5

	Bicuspid aortic valve			
P	lease list all allergies (such	as to drugs, foods, pollen or others)		
	mold, tobacco			
L	ist any other important info	mation about the person (such as smoking, pregnancy, alcoho	ol use, etc.)	
_				
	ist all current prescription r	nedications and medical devices being used.		
	Lexapro 10mg			
	Lexapro 10mg	nedications and medical devices being used.  lications and any vitamins, minerals, supplements, and herbal	remedies being used.	
Li	Lexapro 10mg	lications and any vitamins, minerals, supplements, and herbal	remedies being used.	
Li	Lexapro 10mg ist all over-the-counter me	lications and any vitamins, minerals, supplements, and herbal		
Li	Lexapro 10mg ist all over-the-counter med	lications and any vitamins, minerals, supplements, and herbal in Filling Out This Form		

rimary?	Yes	
Reporter is Patient?		
litle little	21-70-9	
ast name	(b) (6)	
/liddle Name		
irst name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(C. 16)	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
ax		
Reporter Organization		
Department		
Reporter Speciality		

Generated by: SYSTEM Generated on: 30-May-2019 20:16:03 Page 4 of 5

Receipt No: RCT (b) (6)

CTU No: FDA:CDER-CTU-2019 (0X6) | Department: CTP | RCT No: RCT-(b) (6) | CTU Triage Date: 31-05-2019 | Total Pages:

Today's date 03-Apr-2019

Did you report this problem to the company that makes the product (the manufacturer/compounder)?

If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):

Generated by: SYSTEM Generated on: 30-May-2019 20:16:03 Page 5 of 5



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-06-03

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

(b) (6)

(max length: 50 characters)

Voluntary

Type of Submission

**Regulatory Status** 

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

Describe who the problem was reported to

<blank>

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

**Organization Name** <blank> Confirm Email First Name Last Name Did you report the problem No to the manufacturer? Job Title <blank> Phone Email (If prefilled, changing this email address will not change your Login email ID) Country **United States** Street Address Line 1 Street Address Line 2 <blank> City/Town State ZIP/Postal Code Sender Category Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Concerned citizen apply) Describe other consumer/ <blank> concerned citizen type Are you the person who experienced health

Yes

## **Problem Summary**

problems associated with a

tobacco product?

Problem Start Date 04/01/2019

**Problem End Date** 

06/03/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

When exposed to 2nd-hand nicotine vapors, I experience a very disorienting sensation, and I feel numbness in my mouth and face and lose the ability to taste for several minutes, usually about 30 minutes. This is accompanied by itchy/burning throat and lungs.

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

None of the above

Treatment Received (select all that apply)

None

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

30

Select Unit of Time

minute(s)

What is the current status of the health problem?

Other

Describe other current status of health problem

The issue recurs with each exposure.

## **Affected Person**

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

Nonuser(s)

How many nonusers were

affected?

2

Gender

Female

Pregnant

<blank>

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

36

Select Unit of Age

year(s)

Please list any known preexisting health problems for None the affected person

## **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Multivitamin Krill oil

## What are the main symptoms or health problems?

Term describing the health problem

Disorientation

## What are the main symptoms or health problems?

Term describing the health problem

Numbness

# What are the main symptoms or health problems?

Term describing the health problem

Numb mouth

## What are the main symptoms or health problems?

Term describing the health problem

Numbness in face

## What are the main symptoms or health problems?

Term describing the health problem

Numbness oral

## What are the main symptoms or health problems?

Term describing the health problem

Head tightness

## What are the main symptoms or health problems?

Term describing the health problem

Irritation of eyes

# What are the main symptoms or health problems?

Term describing the health problem

Itchy throat

## What are the main symptoms or health problems?

Term describing the health problem

Chest burning

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping <blank> product (including electronic waterpipe)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

<blank>

Does the e-liquid, e-juice or vape juice contain any of the <br/>
<br/>
<br/>
dank> following? (select all that apply)

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

This is a Jul product that looks like a flash drive, and the 2nd-hand residue smells like sweet tobacco.

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

<blank>

What is the country of manufacture of the tobacco <blank> product?

Where is the tobacco product now?

Unknown

How was this product acquired?

From a Friend

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

## **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) <br/>
Country <br/>
<b

Phone <br/>

Street Address Line 1 <br/>
<b

Street Address Line 2 <blank>

City/Town <br/> <blank>

State <br/>

ZIP/Postal Code <br/>
<b

Web Address <br/>

Email Address <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

# **Tobacco Product Use Details**

How was the tobacco product used?	Other
Describe other way the tobacco product was used	2nd hand exposure (inhalation) after another individual vaped.
On average, how often is this tobacco product used?	Rarely
Are other substances being mixed in with the tobacco product when used?	Unknown
Did the problem occur with first time use of the tobacco product?	 blank>
How long has the person been using this type of tobacco product?	    
Select Unit of Measure	   
How soon after the tobacco product was last used did the problem occur?	a l
Select Unit of Measure	Second(s)
How long has the person been using this particular brand or label?	  dank>
Select Unit of Measure	   
Did the person continue to use this tobacco product after the problem occurred?	       
Did this same or similar problem happen again after repeat use of the tobacco product?	Yes
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	Unknown

#### **Tobacco Product Parts**

### Other Products Used

Has the affected person used other tobacco products No (either currently or in the past)?

#### **Other Tobacco Products**

### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. The 1st hand user is a minor who cannot legally purchase the nicotine product. The 2nd hand vape exposure is occurring in a home where all use of tobacco and nicotine is forbidden. The 2nd hand vape is exposing adults, children, and an infant to the unknown residues. The young child and infant cannot articulate any effects of exposure.

### **Attached Files**

None

#### MedWatch 3500B Consumer/Patient Report

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

FDA Safety Report ID #	(in (a)	FDA Received Date	05-Jun-2019	
SECTION A - ABOUT THE PROBLEM				
BESTIVITA - ABOUT THE FROBLEM		Were hurt or had a bad side effect (including new or worsening symptoms)	Yes	
A1. What kind of problem was it?		Used a product incorrectly which could have or led to a problem		
		Noticed a problem with the quality of the product		
		Had problems after switching from one product maker to another maker		
		Hospitalization - admitted or stayed longer	Yes	
		Required help to prevent permanent harm		
		Disability or health problem		
A2. Did any of the following happen?		Birth defect		
		Life-threatening		
		Death (include date)		
		Other serious/important medical incidents (please describe)		
A3. Date the problem occurred:		04-Jun-2019		

CTU No.: FDA-CDER-CTU-2019-150-17 | Department: CTP | RCT No.: RCT-107 (6) | CTU Triage Date: 05-06-2019 | Total Pages

A5. Relevant Tests/Laboratory Data:	
Test1	
Test Date:	04-Jun-2019
	Blood Tests and CT scan
Test Name:	
rest ivalities	
Test Result:	
Test Unit:	
Low Test Range.	
High Test Range:	
Test 2	
Test Date:	
Total Melmon	
Test Name:	
Test Result:	
20.000.000	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 3.	
Test Date;	
-	
Laboration and the second seco	
Test Name:	
Test Result:	
1990 1000	
Total 16.4.	
Test Unit:	
Low Test Range:	
High Test Range: Test 4	
Test Date:	
and an	
Test Name:	
Test Result:	
1 See to see U.	
Test Unit:	11
Low Test Range: High Test Range:	
Trigit real Kalige.	

CTU No.: FDA-CDER-CTU-2019 | Department: CTP | RCT No.: RCT | CTU Triage Date: 05-06-2019 | Total Pages 10

Test Name;  Test Result:  Test Unit:	A5. Relevant Tests/Laboratory Data:	
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Test Result:  Test Unit: Low Test Range: High Test Range: Test 8 Test Date:  Test Name:  Test Result:  Test Result: Low Test Range:	Test Date:	
Test Result:  Test Unit: Low Test Range: High Test Range: Test 8 Test Date:  Test Name:  Test Result:  Test Result: Low Test Range:		
Test Unit: Low Test Range: High Test Range: Test 8 Test Date:  Test Name:  Test Name:  Low Test Result:  Low Test Range:	Test Name:	
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Test Result:  Test Unit:  Low Test Range:	Test Date:	
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Test Unit. Low Test Range:	Test Name:	
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Test Unit. Low Test Range:	Tool Depute	
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Low Test Range:		
Low Test Range: High Test Range:		
High Test Range:	Low Test Range:	
	High Test Range:	

A5. Additional Comments:			
lease select the cause of the problem that	Problem with a product		
	Problem with a product Problem with a device	'Yes	
pplies below:		"Yes	
Please select the cause of the problem that pplies below: SECTION B - PRODUCT AVAILABILITY	Problem with a device	Yes	
pplies below:		Yes	

SECTION C - ABOUT THE PRODUCTS		
Product 1		
	Drug	
C1. This report is about	Cosmetic, Dietary Supplement or Food/Medical Food	
C2. Name(s) of the product as it appears on the box, bottle, or package:		
C3. Check if therapy is on-going		
C4. Name(s) of the company that makes (or compounds) the product:		
	OTC (Over-the-counter)	
C5. Product Type:	Compounded	
Co. Floudet Type.	Generic	
	Biosimilar	
C6. Expiration date:		A
C7. Lot number.		
C8. NDC number.		
C9. Strength:		
C10. Quantity:		
C11. Frequency:		
C12. How was it taken or used?		
C13a. Date the person first started taking or using the product:		- 1
C13b. Date the person stopped taking or using the product:		
C14. Give best estimate of duration:		
C15. Why was the person using the product?		
C16. Did the problem stop after the person reduced the dose or stopped taking or using the product?		
C17. Did the problem return if the person started taking or using the product again?		1

Product 2			
1100000	Drug		
C1. This report is about	Cosmetic, Dietary Supplement or Food/Medical Food		
C2. Name(s) of the product as it appears on the box, bottle, or package:		,	
C3. Check if therapy is on-going			
C4. Name(s) of the company that makes (or compounds) the product			
	OTC (Over-the-counter)		
C5. Product Type:	Compounded	= 1 =	
co. Froduct type.	Generic		
	Biosimilar		
C6. Expiration date:		4	
C7. Lot number:			
C8. NDC number:		. V.	
C9. Strength:	1		
C10. Quantity:			
C11. Frequency:		1	
C12. How was it taken or used?			
C13a. Date the person first started taking or using the product			
C13b. Date the person stopped taking or using the product			
C14. Give best estimate of duration:	1		
C15. Why was the person using the product?		*	
C16. Did the problem stop after the person reduced the dose or stopped taking or using the product?			
C17. Did the problem return if the person started taking or using the product again?			

SECTION D - ABOUT THE MEDICAL DEVICE				
D1. Name of medical device:	Juni			
D2. Name of the company that makes the medical device:	Juul Labs			
D3. Model number:				
D4. Catalog number:				
D5. Lot number:				
D6. Serial number:				
D7. UDI number:				
D8. Expiration date:				
D9. Was someone operating the medical device when the problem occurred?	Yes			
	The person who had the problem	Yes		
D9. If yes, who was operating it?	A health professional (such as a doctor, nurse, or alde)		_	
	Someone else (Please explain who):	1		
D10. Date the implant was put in:				
D10. Date the implant was taken out:				

E1. Person's Initials:			
	Female	Yes	
	Male		
E2. Gender.	Intersex		
	Transgender		
	Prefer not to disclose		
E3. Age:	17	Year(s)	
E4. Date of Birth:		1	
E5. Weight:	98	llo	
202000	Hispanic/Latino	- 1 -	
E6. Ethnicity:	Not Hispanic/Latino	Yes	
	Asian		
	American Indian or Alaskan Native		
EI Bara	Black or African American		
E7. Race:	White	Yes	
	Native Hawaiian or Other Pacific Islander		

E8. List known medical conditions:	
anxiety	
E9. Please list all allergies:	
tree nuts, shellfish, reflex, penicillin	
E10. List any other important information about the person:	

st all over-the-counter medications and any vitamins, minerals, supplements, and herb	al remedies being used:

SECTION F - ABOUT THE PERSON FILLING OUT THIS F	FORM
F1. Last Name	DIG.
F2. First Name	
F3. Number/Street	(G) (O)
F4. City and State/Province	
F5, ZIP or Postal Code	( NOT
F6. Country	US
F7. Telephone number	(0)(0)
F8. Email address	(0) (6) 1000
F9. Today's date	05-Jun-2019
F10. Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
F11. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box (Confidentiality Requested):	No.

Receipt No: RCT 60 6 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-10-00 | Department: CTP | RCT No.: RCT-(b) | D | CTU Triage Date: 07-06-2019 | Total Pages: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Company U	Jnit	CDER-CTU	Originating Account	FAERS
Source Me		MWO (Drug)	Source Form Type	E2B XML 3500B
Priority		Routine	The marks of the Sales	The second section of the second of
-	uto Calculation Rule	No		
FDA Recei	ved Date	06-Jun-2019	CTU Received Date	07-Jun-2019
CTU Triage	e Date	444444	CTU Data Entry Date	
Report Typ	oe e	Spontaneous	Report Classification	Drug
Assign To		User	Ą-	
User/Group	p			
Forward to	Department	CDER (CDER-O	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priori	ity	Direct		
Contact	V	7-7	77-107	
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)
	- About the Problem		)	
Date the problem occurred Serious Did any of the following happen? (Check all that apply)		The second secon	nt permanent harm	er
	vhat happened and hov onal documents if nece	Other serious/important	t medical incident(Please Describe Below) de as many details as possible F	FDA may reach out to you fo
4.Tell us w any additio	onal documents il nece	22211		
A couple have a	e minutes after hitting a Ju	ıul, I experienced a seiz	zure. I don't know if the two are relate tress, and getting very littles sleep, so	
A couple have a phave led	e minutes after hitting a Ju past history of seizures. I'v	ıul, I experienced a seiz		
A couple have a phave led	le minutes after hitting a Ju past history of seizures. I'v d to my seizure. Fest/Laboratory Data	ıul, I experienced a seiz		that paired with the Juul may
A couple have a have led	le minutes after hitting a Ju past history of seizures. I'v d to my seizure. Fest/Laboratory Data	ıul, I experienced a seiz	tress, and getting very littles sleep, so	that paired with the Juul may
A couple have a have led	le minutes after hitting a Ju past history of seizures. I'v d to my seizure. Fest/Laboratory Data	ıul, I experienced a seiz	tress, and getting very littles sleep, so	that paired with the Juul may

Receipt No.: RCT (6) (6)
CTU No.: FDA-CDER-CTU-2018 | Department: CTP | RCT No.: RCT (6) | CTU Triage Data: 07-06-2019 | Total Pages: 5 FDA 3500B Form

ditional Comments			
ction B - Product Availability			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the product? (check yes if you are including a picture)	No		
ction C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Drug		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Mint Juul pods 5% strengt	th	
Name of the company that makes (or compounds) the product	Juul Vapor		
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmac Generic Biosimilar	y or an Outsourcing Facility	
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?	Doesn't Apply		
ug Therapy			1 of 1
Expiration date			
Lot number	Ji ree		
Dosage Form			
Quantity		If Other	ri -
Frequency		If Other	
How was it taken or used	Respiratory (inhalation)	If Other	
Date the person first started taking or using the product	16-Mar-2018	*	*
Date the person stopped taking or using the product	06-Jun-2019		
Give best estimate of duration			

Generated on: 07-Jun-2019 00:15:25 Page 2 of 5 Receipt No: RCT-101 16 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2019-CKO | Department: CTP | RCT No.: RCT b) (6) | CTU Triage Date: 07-06-2019 | Total Pages: 5

Is therapy still on-going?	
Vhy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1
Recreation	
Returned to Manufacturer On	
Returned to Manufacturer Off	
Section D - About the Medical De	evice
Name of medical device	
Name of the company that makes the medical device	
	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
ocate them)	
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	
For implented modical devices C	NLY (such as pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If
Date the implant was put in	relevant)
Section E - About the Person Wr	so Had the Broklem
Person's Initials	to had the Problem
Gender	Male
Age (specify unit of time for age)	20 Year(s)
Date of Birth	20 fear(s)
I I I Y Y O'LE CA Y O'	00.051.4
Weight	86.85 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	American Indian or Alaskan Native
	Native Hawaiian or Other Pacific Islander
	L. Asian
	White
	Black or African American

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

	None	
PI	lease list all allergies (such as to drugs, foods, pollen or others)	
	None	
	I st any other important information about the person (such as smoking, pregnancy, alc	cohol use, etc.)
	Marijuana	
Lis	st all current prescription medications and medical devices being used.	
	None	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and her	bal remedies being used.
	None	
9-9-		

tion F - About the Persor		1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(0) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	E (0)	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		

Receipt No: RCT(b) (6) FDA 3500B Form

FDA 3500B Form
CTU No.: FDA-CDER-CTU-2018(b) (6) | Department: CTP | RCT No.: RCT-(b) (6) | CTU Triage Date: 07-06-2019 | Total Pages: 5

Today's date	06-Jun-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 07-Jun-2019 00:15:25 Page 5 of 5



#### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-06-08

FDA ICSR ID (b) (6)

Report Key for Followup

(b) (6)

Proxy Report Information (not applicable if this is not a proxy report)

## 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 Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

### **Contact Information - Sender**

Organization Name <br/>

Confirm Email (b) (6)

First Name

Last Name (b) (6)

Did you report the problem to the manufacturer?

Job Title <br/>
Phone <br/>
<b

Email (If prefilled, changing this email address will not change your Login email ID)



Country United States

Street Address Line 1 <br/>
Street Address Line 2 <br/>
City/Town <br/>

State <br/>
ZIP/Postal Code <br/>
<b

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that Consumer

apply)

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

Yes

## **Problem Summary**

Problem Start Date 02/26/2019

Please describe the health Simple partial seizure lasting 30 seconds after using vape first thing problem or product problem. In the morning, involved loss of motor functions and uncontrollable

The Attachments page will accept uploads of any records, pictures, or other information.

shaking while still aware/conscious. Occurs about once or twice a month.

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

None of the above

Treatment Received (select all that apply)

None

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

5

Select Unit of Time

month(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

1

Gender

Female

Pregnant

No

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

22

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person

None

## **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

None

## What are the main symptoms or health problems?

Term describing the health problem

Partial seizures, simple

#### **Tobacco Products**

Tobacco Product Type

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased for use in a capsule, tank or refillable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s)

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Fruit

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Smok novo filled with Pacha Mama 50 mg nicotine salt (flavor sorbet)

When did the person purchase this product?

12/04/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco product?

<blank>

Where is the tobacco product now?

User/Consumer has the product

How was this product acquired?

In a Store

Do you know where the product was purchased?

Yes

Manufacturer Name

<blank>

## **Tobacco Product Packaging and Portions**

Manufacturer Investigation Information

#### **Tobacco Product Purchase Location**

**Purchase Location Name** <blank> Country <blank> Phone <blank> Street Address Line 1 <blank> Street Address Line 2 <blank> City/Town <blank> <blank> State ZIP/Postal Code <blank> Web Address <blank> **Email Address** <blank>

### Tobacco Product Manufacturer Information

## **Tobacco Product Use Details**

How was the tobacco Inhaled (smoked or vaped) product used?

On average, how often is Every Day this tobacco product used?

Are other substances being mixed in with the tobacco No

product when used?

Did the problem occur with first time use of the tobacco No product?

How long has the person been using this type of tobacco product?

Select Unit of Measure

Month(s)

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

Select Unit of Measure Minute(s)

How long has the person been using this particular brand or label?

5

Select Unit of Measure Month(s)

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

#### **Tobacco Product Parts**

## Other Products Used

Has the affected person used other tobacco products (either currently or in the past)?

#### Other Tobacco Products

**Tobacco Product Type** 

Cigarette

**Full Tobacco Product Name** including Brand and Sub-

<blank>

Brand (if unknown, please enter "unknown")

Is the tobacco product currently being used?

No

## **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

## **Attached Files**

None



#### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-06-12

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## 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 Problem associated with a tobacco product (not associated with a product problem or defect)

itting? a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

### **Contact Information - Sender**

**Organization Name** <blank> **Confirm Email** First Name Last Name Did you report the problem No to the manufacturer? Job Title Phone Email (If prefilled, changing this email address will not change your Login email ID) Country United States Street Address Line 1 Street Address Line 2 City/Town State ZIP/Postal Code Sender Category Healthcare Professional (FdaTPR) Healthcare Professional type Physician Are you the person who experienced health No problems associated with a

Describe your relationship to the person who experienced the health problem

tobacco product?

2 of my patients experienced an issue

## **Problem Summary**

Problem Start Date <br/>

#### **Problem End Date**

<blank>

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information. I have had 2 patients who have had syncopal episodes after using the Juul or a vape pen. One possible had a seizure. The first was a 19 year old male who passed out in March 2019 after using Juul on 2 different occasions. The 2nd time he fell on the stairs and suffered a concussion. He was seen by a cardiologist and had a normal exam. He also had a MRI of his brain because he had delayed vomiting after his fall. The second was a 15 year old female who use an older person's vape pen that had THC per the patient which was legally bought. She passed out after and had possible loss of bladder control. She is going to see a neurologist and cardiologist.

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

None of the above

Treatment Received (select all that apply)

Healthcare Professional Visit, Emergency Room Visit Without Hospital Admission

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Please see above. Both patients received an EKG. The male had a MRI of his brain. The female had a normal EKG, blood and urine results in the ER. She is still waiting to see the cardiologist and neurologist.

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)

What is the current status of the health problem?

Recovered or Resolved

### Affected Person

Affected Person Identifier Code (4) (4)

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were

affected?

2

Gender

Other

Pregnant

<blank>

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem

<blank>

Age of the person when the

problem occurred

15

Select Unit of Age

year(s)

Please list any known pre-

existing health problems for none known

the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Birth control for the female

## What are the main symptoms or health problems?

Term describing the health problem

Syncope

### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype	E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer
Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)	  dank>
Select all that apply to the e- liquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product	                   
Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)	  dank>
Was the e-liquid dripped on to the atomizer or heating element?	  dank>
Full Tobacco Product Name, including Brand and Sub- Brand (if unknown, please enter "unknown")	unknown
When did the person purchase this product?	  dank>
UNIVERSAL PRODUCT CODE (UPC) from Label	    
Does the involved product device or package bear the "UL" symbol?	  dank>
Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)	   
What is the country of manufacture of the tobacco product?	   

Where is the tobacco

How was this product

Do you know where the

product was purchased?

product now?

acquired?

<blank>

<blank>

No

## **Tobacco Product Packaging and Portions**

## **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### Tobacco Product Manufacturer Information

### **Tobacco Product Use Details**

How was the tobacco product used?

On average, how often is

this tobacco product used?

Are other substances being mixed in with the tobacco product when used?

Describe what substances are being mixed with the tobacco product

Did the problem occur with first time use of the tobacco <blank> product?

Inhaled (smoked or vaped)

Rarely

Yes

alcohol

How long has the person been using this type of tobacco product?

<blank>

Select Unit of Measure

<blank>

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

<blank>

Select Unit of Measure

<blank>

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

Unknown

### **Tobacco Product Parts**

### Other Products Used

Has the affected person used other tobacco products (either currently or in the past)?

# **Other Tobacco Products**

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

# **Attached Files**

None



#### REPORT INFORMATION

### Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-06-25

FDA ICSR ID b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

## Report Identifying Information

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

**Regulatory Status** Voluntary Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

# **Contact Information - Sender**

Organization Name	(b) (6)
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	No
Job Title	(b) (6)
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	<blank></blank>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Healthcare Professional (FdaTPR)
Healthcare Professional type	Pharmacist
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health	Sister

# **Problem Summary**

problem

Problem Start Date

02/01/2018

#### **Problem End Date**

#### 06/25/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information. AES began using a Juul around February of 2018. Since she started using the e-cigarette, she has experienced episodes 1-5 times per month in which she loses consciousness for a few seconds, usually with her eyes open and with a blank stare. On 6/23/2019, AES was driving and using the e-cigarette when she experienced a more severe seizure and crashed her car resulting in non-life threatening injuries. AES received a full work-up at the local hospital, which found no etiology for the seizure incident.

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

Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

AES was taken to a local emergency room where they performed a full work-up including blood work, CT Scan, MRI, MRA, EEG, and Echo cardiogram. All results were normal with no abnormalities. AES did not experience another partial seizure throughout the hospital stay of approximately 40 hours

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

40

Select Unit of Time

hour(s)

What is the current status of the health problem?

Recovered or Resolved

## **Affected Person**

Affected Person Identifier Code



Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

4

Gender Female

Pregnant No

Race (Select all that apply) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the problem

Age of the person when the

problem occurred

20

Select Unit of Age

year(s)

Please list any known preexisting health problems for N/A

the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

N/A

# What are the main symptoms or health problems?

Term describing the health problem

Seizure

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)

Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Puff/flow activated

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Glycerin, Propylene Glycol, Other

Describe other e-liquid ingredients

benzoic acid

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Mint (such as wintergreen or spearmint), Fruit, Combination/mixture of flavors

Was the e-liquid dripped on to the atomizer or heating element?

Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

JUUL Device JUULpods

When did the person purchase this product?

02/01/2018

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

Don't Know

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)

JUUL Device: lost in car crash JUULpods: HE06GA03A

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Unknown

How was this product

acquired?

In a Store

Do you know where the product was purchased?

No

Manufacturer Name

Other

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) Juul Labs, Inc.

Country United States

Phone <br/>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <br/> <b

State <br/>

ZIP/Postal Code <br/>
<b

Web Address <br/> <br/>

Email Address <br/>
<br/

#### **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

No

Describe what substances are being mixed with the tobacco product

<blank>

Did the problem occur with first time use of the tobacco Yes product?

How long has the person been using this type of tobacco product?

<blank>

Select Unit of Measure

<blank>

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

45

Select Unit of Measure

Second(s)

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

No

Did this same or similar problem happen again after repeat use of the tobacco product?

N/A - Person did not restart use

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

No

#### **Tobacco Product Parts**

#### Other Products Used

Has the affected person used other tobacco products Yes (either currently or in the past)?

#### **Other Tobacco Products**

Tobacco Product Type Cigarette

Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Is the tobacco product currently being used?

No

#### Additional Information

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. AES is an otherwise healthy 20 year old female. Since she began using the JUUL device, she started having episodes that are consistent with seizures. AES used the JUUL all day long, and always when she was driving. Since the car crash due to a partial seizure while driving on 06/23/2019, AES has not used the JUUL and has not had another episode.

#### **Attached Files**

None



# REPORT INFORMATION

# Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

**Submitted** 2019-06-25

FDA ICSR ID (b) (6)

Followup by using your

account



# Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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



Regulatory Status Voluntary

Type of Submission Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

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

**Organization Name** <blank> **Confirm Email** First Name Last Name Did you report the problem <blank> to the manufacturer? Job Title Phone Email (If prefilled, changing this email address will not change your Login email ID) United States Country Street Address Line 1 Street Address Line 2 <blank> City/Town D) (6) State ZIP/Postal Code Sender Category Consumer/Concerned Citizen (FdaTPR) Consumer/Concerned Citizen Type (select all that Other apply) Describe other consumer/ Mother of a teenager consumer concerned citizen type Are you the person who experienced health <blank> problems associated with a

# **Problem Summary**

tobacco product?

Problem Start Date 12/20/2017

**Problem End Date** 

<blank>

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Seizures started up way different then when she had them at age 12. She started having Gran Mals and up to 15 a day. She was also very depressed, anxiety, no motivation or care and crazy mood swings. She started cutting her thighs and couldn't be left alone as she was so depressed we feared suicide. She had to be withdrawn from school.

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

Lasting disability or other permanent health problem, Life threatening, Hospitalization (overnight or longer)

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

She has been in and out of hospitals and has seen multiple doctors and multiple tests. Too much to write down.

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

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

<blank>

# Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

User(s)

How many users were affected?

7

Gender

Female

Pregnant

No

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

14

Select Unit of Age

year(s)

Please list any known preexisting health problems for the affected person was diagnosed with seizures at age 11. She only had them for about a month. She was off medication for almost 2 years and they started back up when she started smoking the Juul.

# **Medications and Supplements**

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Vimpat Zomisimide CBD Oil Trileptal Lamictal

# What are the main symptoms or health problems?

Term describing the health problem

Tonic-clonic seizures

#### What are the main symptoms or health problems?

Term describing the health problem

Depression

#### **Tobacco Products**

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, **Tobacco Product Type** e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporízers; E-liquids, e-juice or vape juice) E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal **Tobacco Product Subtype** vaporizer Select all that apply to the electronic cigarette, Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Uses refillable cartridge, cart, cartomizers or carto (that are filled electronic nicotine or vaping product (including electronic by the user) waterpipe) Select all that apply to the eliquid, e-juice or vape juice Purchased in a non-refillable disposable cartridge, Purchased for use in for your electronic cigarette, a capsule, tank or refillable cartridge electronic nicotine or vaping product Does the e-liquid, e-juice or vape juice contain any of the Nicotine, Coloring Agents, Flavor(s), Glycerin, Propylene Glycol, Water following? (select all that apply) Describe other e-liquid <blank> ingredients What type(s) of flavor(s) Tobacco, Menthol, Mint (such as wintergreen or spearmint), Fruit, does the e-liquid contain? Candy or Chocolate, Combination/mixture of flavors (select all that apply) Was the e-liquid dripped on to the atomizer or heating Unknown element? Full Tobacco Product Name, including Brand and Sub-Juul Brand (if unknown, please enter "unknown") When did the person <blank> purchase this product? UNIVERSAL PRODUCT <blank> CODE (UPC) from Label Does the involved product device or package bear the Don't Know "UL" symbol? Any other identifying tobacco product codes (for <blank> example, SKU, item/catalog

number, manufacturing date/ batch code)

What is the country of

manufacture of the tobacco United States

product?

Where is the tobacco product now?

Product was discarded

How was this product

acquired?

From a Friend

Do you know where the product was purchased?

No

Manufacturer Name

<blank>

# **Tobacco Product Packaging and Portions**

# **Manufacturer Investigation Information**

#### **Tobacco Product Purchase Location**

# **Tobacco Product Manufacturer Information**

# **Tobacco Product Use Details**

How was the tobacco product used?

Inhaled (smoked or vaped)

On average, how often is this tobacco product used?

Every Day

Are other substances being mixed in with the tobacco product when used?

Did the problem occur with first time use of the tobacco product?

How long has the person been using this type of tobacco product?

Select Unit of Measure <br/>
Shank>

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

<blank>

Select Unit of Measure

<blank>

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

Yes

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

## **Tobacco Product Parts**

#### Other Products Used

Has the affected person No used other tobacco products

(either currently or in the past)?

# **Other Tobacco Products**

# **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

<blank>

# **Attached Files**

None



#### REPORT INFORMATION

## Report Profile

Report Version FPSR.FDA.CTP.V.V3

Report Category Tobacco Product Report V3

Submitted 2019-06-29

FDA ICSR ID (b) (6)

Report Key for Followup

Proxy Report Information (not applicable if this is not a proxy report)

# Report Identifying Information

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

(b) (6

(max length: 50 characters)

Voluntary

Regulatory Status

Type of Submission

Initial

What type of report are you

submitting?

Health Problem associated with a tobacco product (not associated with

a product problem or defect)

Did you report this problem somewhere else (outside No SRP)?

#### Contact Information - Sender

**Organization Name** <blank>

Confirm Email <blank>

First Name <blank>

Last Name <blank>

Did you report the problem

to the manufacturer?

<blank>

Job Title <blank>

Phone <blank>

Email (If prefilled, changing

this email address will not change your Login email ID) <blank>

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Sender Category Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned

Citizen Type (select all that Concerned citizen

apply)

Are you the person who experienced health problems associated with a

tobacco product?

Yes

# **Problem Summary**

**Problem Start Date** 06/01/2019

**Problem End Date** 06/29/2019

Please describe the health

I experience tachycardia, exceeding 100 bpm at rest when my teen problem or product problem. son enters the home with vape residuals on his clothing and when he The Attachments page will accept uploads of any records, pictures, or other information. had a sealed container of Glasvapor nicotine liquid in his bedroom. I experience tachycardia and other symptoms, such as numbness and nervous ticks in my mouth and face even when in the presence of sealed containers at a distance greater than 10 ft.

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

None of the above

Treatment Received (select all that apply)

Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

Removed from presence of offending substance.

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

4

Select Unit of Time

week(s)

What is the current status of the health problem?

Not Recovered or Unresolved

#### Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.)

Nonuser(s)

How many nonusers were

affected?

1

Gender

Female

Pregnant

No

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the problem



Age of the person when the problem occurred

Select Unit of Age

year(s)

Please list any known preexisting health problems for <blank> the affected person

# **Medications and Supplements**

Please list the prescription medications, over-thecounter medications, vitamins, and/or supplements taken around the time of the health problem.

Krill oil Multivitamin

# What are the main symptoms or health problems?

Term describing the health problem

Numbness facial

# What are the main symptoms or health problems?

Term describing the health problem

Wheezing

# What are the main symptoms or health problems?

Term describing the health problem

Numbness of tongue

# What are the main symptoms or health problems?

Term describing the health problem

Tachycardia

# What are the main symptoms or health problems?

Term describing the health problem

Burning in eyes

# What are the main symptoms or health problems?

Term describing the health problem

Disorientation

# What are the main symptoms or health problems?

Term describing the health problem

Nausea

# What are the main symptoms or health problems?

Term describing the health problem

Muffled hearing in both ears

# What are the main symptoms or health problems?

Term describing the health problem

Head tightness

# What are the main symptoms or health problems?

Term describing the health problem

Movements spastic involuntary

# What are the main symptoms or health problems?

Term describing the health problem

Abnormal involuntary movements

#### **Tobacco Products**

**Tobacco Product Type** 

Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal

vaporizers; E-liquids, e-juice or vape juice)

**Tobacco Product Subtype** 

E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the eliquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product

Mixed in a shop or on-line per request or "to order"

Describe the e-liquid mix

Glas vapor 100 ml Crystal bottle. Flavor unknown.

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)

Nicotine, Flavor(s), Other

Describe other e-liquid ingredients

Unknown

What type(s) of flavor(s) does the e-liquid contain? (select all that apply)

Other

Describe other e-liquid

flavor(s)

Baked goods

Was the e-liquid dripped on to the atomizer or heating element?

No

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

Glas vapor crystal series

When did the person purchase this product?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Does the involved product device or package bear the "UL" symbol?

No

Any other identifying tobacco product codes (for

example, SKU, item/catalog number, manufacturing date/

<blank>

batch code)

What is the country of manufacture of the tobacco product?

**United States** 

Where is the tobacco product now?

Product was discarded

How was this product acquired?

<blank>

Do you know where the product was purchased?

Yes

Manufacturer Name

Other

# **Tobacco Product Packaging and Portions**

Manufacturer Investigation Information

#### **Tobacco Product Purchase Location**

Purchase Location Name Glas LLC

Country United States

Phone (310) 510-6230

Street Address Line 1 2127 Westwood Blvd.

Street Address Line 2 <blank>

City/Town Los Angeles

State California

ZIP/Postal Code <br/>
<b

Web Address https://glasvapor.com/collections/100ml-crystal-bottle

Email Address <br/>
<br/

#### **Tobacco Product Manufacturer Information**

Manufacturer Name (Other) <br/>
<br/

Country <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/> <br/>

Phone <br/>

Street Address Line 1 <br/>
<b

Street Address Line 2 <blank>

City/Town <br/> <blank>

State <br/>

ZIP/Postal Code <br/>
<b

Web Address <br/>

Email Address <br/>
<br/

#### **Tobacco Product Use Details**

How was the tobacco product used?

Other

Describe other way the tobacco product was used

Adverse effects from remote exposure to a sealed container

On average, how often is this tobacco product used?

Rarely

Are other substances being mixed in with the tobacco product when used?

<blank>

Did the problem occur with first time use of the tobacco product?

Yes

How long has the person been using this type of tobacco product?

<blank>

Select Unit of Measure

<blank>

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

<blank>

Select Unit of Measure

<blank>

How long has the person been using this particular brand or label?

<blank>

Select Unit of Measure

<blank>

Did the person continue to use this tobacco product after the problem occurred?

<blank>

Did this same or similar problem happen again after repeat use of the tobacco product?

Yes

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

No

#### **Tobacco Product Parts**

Full Tobacco Product Part Name, including Brand and Sub-Brand (if unknown, please enter "unknown")

<blank>

Tobacco Product Part Type <br/>
<br/

When was this tobacco product part purchased or acquired?

<blank>

UNIVERSAL PRODUCT CODE (UPC) from Label

<blank>

Any other identifying tobacco product part codes(e.g. SKU, item/catalog number)

<blank>

What is the country of manufacture of the tobacco product part?

<blank>

Where is the tobacco product part now?

<blank>

Do you know who manufactured this tobacco product part?

Yes

#### **Tobacco Product Part Purchase Location**

How was this tobacco product part acquired?

Purchase Location Name

Country <br/> <br/> <br/> <br/> <br/> <br/>

Phone <br/> <br/> <br/> <br/> <br/> <br/>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town (b) (6)

State (b) (c)

ZIP/Postal Code <br/>
<b

Web Address <br/>

Email Address <br/>
<br/

#### **Tobacco Product Part Manufacturer Information**

Manufacturer Name Other

Manufacturer Name (Other) Glas LLC

Country United States

Phone (310) 510-6230

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town LOS ANGELES

State California

State/Province <br/>
<br

ZIP/Postal Code <br/>
<b

Web Address <br/>

Email Address <br/>
<br/

#### Other Products Used

Has the affected person used other tobacco products No (either currently or in the past)?

#### **Other Tobacco Products**

#### **Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. From more than 10 feet away, I have adverse reactions described while the nicotine liquid is in a sealed primary container, a sealed Ziploc secondary container, and a tertiary sealed glass jar. I do not use nor have I ever used this product or any nicotine liquid. My 17 year old son is sneaking it into our home. It's not lawful for him to purchase.

It's forbidden in our home. I have terrible health effects from remote contact. Please remove this product from market until thorough review of safety.

# **Attached Files**

FILENAME Screenshot\_2019-06-29-02-37-47.png

**Description of Attachment** 

Attachment Type Other

U.S. Department of Health and Human Service		IRS	Fo	m Approved:		0-0291, Expires 10/31/0
MEDWATC	adverse events, pro	ARY reporting of oduct problems and use errors	Triage unit	(b)(6)	DA USE ON	MB statement on reverse
The FDA Safety Information and	Internet Submission - D		sequence			
Adverse Event Reporting Progra A. PATIENT INFORMATION	ım	D. SUSPECT PRO	DUCTISA			7
1 Retient identifier 2. Age at Time of Ev		1. Name, Strength, Mari	ulacturer (Irom)	roduct label)		
Date of Birth:	Female 18 to	* e cigaret	te 1		1	
In confidence 8 Mon	☐ Male orkg	#2				
B. ADVERSE EVENT. PRODUC	T PROBLEM OR ERROR	2. Dose or Amount		Frequency		Route
	oblem (e.g., defects/mailunctions)	wt				
	ith Different Manufacturer of Same Medicine	#2	===			
2. Outcomes Altributed to Adverse Event	transfer to the second of the	**				
(Check all that apply)		3. Dates of Use(If unknown best estimate)	own, give duration	) from/to (or		bated After Use d or Dose Reduced?
Death: (mm/ad/yyyy)	Disability or Permanent Damage	**	4-		1973	e TNo Doesn'
Life-threatening	Congenital Anomaly/Birth Defect			_	-	Apply Doesn'
Hospitalization - initial or prolonged	✓ Other Serious (Important Medical Events)	4. Diagnosis or Reason	for Use /Indical	lon)	WZ Ye	No Apply
A STATE OF THE PARTY OF THE PAR	manent Impaliment/Damege (Devices)	#1	The Individual	13		leappeared After duction?
3. Date of Event (mm/dd/yyyy) 08/14/2011	4. Date of this Report (mm/dd/yyyy) 09/27/2011					s No Doesn'
100000000000000000000000000000000000000	717 E 78 V V V	#2 6. Lot #	7. Expiratio	Date	-	Apply  Doesn't
5. Describe Event, Problem or Product Us Our child developed v	The state of the s	1	100	n Date	#2 \ Ye	No Apply
	ion while on vacation	**	#1		9. NDC # 6	or Unique ID
in the UK - manifeste	ed as a recurrent,	*2	#2			
	der shrug. This faded	E. SUSPECT ME	DICAL DEVI	CE		-
after return to the I	I believe this is due	1. Drand Name				
to secondhand exposur		2. Common Device Nar	me			
	tronic cigarette. Her	3. Manufacturer Name, City and State				
father uses an e ciga prior to her adverse						
	While on vacation in	4. Model #	Lot		1	5. Operator of Device
London, he began using the device inside		5. 1040.5				Health Professional
our hotel room, becau	use of questionable s during the riots. On	Catalog 8	Expiration Date			
return to the US, he comfortable with its	Serial #				Other:	
Comportable with 105	apparencity said	6. If Implanted, Give Da	te (mm/dd/yyyy)	7. # Ex	planted, Glvs	Date (mm/dd/yyyy)
		50 to 4 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5		The state of	22-73-31, 2-13	
	1	8, is this a Single-use C	Device that was	Reprocessed	and Reused	on a Patient?
		9. If Yes to Item No. 8, 1	Enter Name and	Address of F	Reprocessor	_
		The state of the s				
6. Relevant Tests/Laboratory Data, Includ						
	RECEIVED					
	1ECEIVED					
		F. OTHER (CONC	COMITANT)	MEDICAL	PRODUCT	rs
	SEP 28 2011	Product names and the	The state of the s	-	September 1	
N.	MEDWATCH CTU					
	ILD III.					
<ol> <li>Other Relevant History, Including Pree- race pregnancy, smoking and alcohol use</li> </ol>	xisting Medical Conditions (e.g., allergies,	C 05000 FFD	The same of the sa	was and the second		NAV.
race pregnancy, smoking and accine usi	a livernamey problems, etc.)	G. REPORTER (S	see confide	itiality sec	tion on ba	аск)
		/ <b>L</b>	101			
X	1					
		1	1-1			
		Phone (b) (6)		E-mail	(6 i	
C. PRODUCT AVAILABILITY		2. Health Professional?				Also Reported to:
Product Available for Evaluation? (Do not	send product to FDA)	Yes No	Phar	maci	st	Manufacturer
✓ Yes ☐ No ☐ Returned to	Manufacturer on:	5. If you do NOT want y				User Facility
	(mm/ad/yyyy)	to the manufacturer,	place an "X" in	this box:		Distributor/Importer





For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

в	5.	Describe	event or	problem	continued

us and gradually increased the proximity and duration of its use near our infant. After discontinuing its use indoors, our daughter's spasm has not recurred. She has had no other symptoms of nicotine toxicity to my knowledge.

Mall to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787

1-800-FDA-0178

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





For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 6

Internet Submission - Page 6

Drug	Manufacturer	Dose	Unit	Route	Dosage	requenc Interval	y Unit	Is Con- comitant
-	+	-	-	_		-		-

Start Date	End Date	Duration	Unit
		0.1	
		-	
			Start End Duration

#### FDA Comments:

wilsonj:   ********   2011-09-28-09.02.26   USFDAMWVOLUNTARY   01 6		
Send copy to Center or Tobacco Products		

MEDWATCH or FAX to: 5600 Fishers Lane 1-800-FDA-0178 Rockville, MD 20852-9787 Mall to: MEDWATCH

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