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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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?	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 pre-existing 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-the-counter 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

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
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)	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 product?	No

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?	1
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, removing a filter from a cigarette)?	No

Tobacco Product Parts

Other Products Used

Other Tobacco Products

Additional Information

Attached Files

None

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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 SRP)?	No

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, 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 teen daughter experienced the health problems

Problem Summary

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 sleep-deprived 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 quit 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	<blank>
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	16
Select Unit of Age	year(s)
Please list any known pre-existing 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)	<blank>
Select all that apply to the e-liquid, 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?	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?	<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?	<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 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>
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

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

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

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	<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>
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

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?	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	22
Select Unit of Age	year(s)
Please list any known pre-existing 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.	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 e-liquid, 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	<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 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)?	Yes

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

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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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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 problems associated with a tobacco product?	Yes

Problem Summary

Problem Start Date	10/16/2018
Problem End Date	10/16/2018
Please describe the health problem or product problem.	I was using a Juul E Cigarette device and after 1 hit of it, I blacked out 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	16
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	Reynauds

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	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)	Uses prefilled cartridge, cart, cartomizers or carto.
Select all that apply to the e-liquid, 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	<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?	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?	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, 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)?	No

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

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Report Identifying Information

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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	Doctors

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<blank>
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)	Other, Consumer, 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	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 pre-existing 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 e-liquid, 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?	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?	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)
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")	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)?	No

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	(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 SRP)?	No
Describe who the problem was reported to	<blank>

Contact Information - Sender

Organization Name	<blank>
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	<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	<blank>
State	(b) (6)
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	02/09/2018
Problem End Date	<blank>
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?	1
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	(b) (6)

Age of the person when the problem occurred	32
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	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, 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,	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 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>
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?	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)?	Yes

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<blank>
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	(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)	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	<blank>
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?	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 pre-existing health problems for the affected person	Random migraines. Unrelated.

Medications and Supplements

Please list the prescription medications, over-the-counter 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

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 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), 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	<blank>
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 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?	<blank>

Tobacco Product Part Purchase Location

How was this tobacco product part acquired?	<blank>
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	<blank>
State/Province	<blank>

Other Products Used

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

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?	<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	(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?	Both (health problem that is also associated with a product problem or defect)

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

Contact Information - Sender

Organization Name	<blank>
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	(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

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?	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	33
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-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	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 product (including electronic waterpipe)	Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user)
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)	Tobacco
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?	06//2015
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	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 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?	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)?	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	(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 SRP)?	No

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>
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)	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 pre-existing 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.	None

What are the main symptoms or health problems?

Term describing the health problem	Focal 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	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), Uses a tank

product (including electronic waterpipe)	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 e-liquid, 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 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)	No
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>
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?	<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>
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?	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	(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 SRP)?	No

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	<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	<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 problem or product problem.	Had hit juul a few times prior to falling asleep, have been juuling 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	(b) (6)
Age of the person when the problem occurred	17
Select Unit of Age	year(s)
Please list any known pre-existing 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 e-liquid, 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)	Tobacco, Menthol, Mint (such as wintergreen or spearmint), 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")	Juul Labs
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?	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 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
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?	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)?	Yes

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>
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")	<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	(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 SRP)?	No

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 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 problem or product problem.	I experienced three seizures, and i believe they all may have been 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?	1
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 pre-existing health problems for the affected person	ADHD

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

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")	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 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?	<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

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

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

Contact Information - Sender

Organization Name	<blank>
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	<blank>
Street Address Line 2	<blank>
City/Town	<blank>
State	(b) (6)
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?	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?	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	35
Select Unit of Age	year(s)
Please list any known pre-existing 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	Fainting

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 e-liquid, 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)	Tobacco, 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")	Juul
When did the person purchase this product?	02/24/2019
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?	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>
Country	United States
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	(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 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	(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	(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	09/08/2018
Problem End Date	09/30/2018
Please describe the health problem or product problem.	Morning of September 8th while in the shower had a black out/seizure; 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	<blank>
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	57
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	High blood pressure arthritis back pain

Medications and Supplements

Please list the prescription medications, over-the-counter 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

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 e-liquid, 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 "UL" symbol?	<blank>
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 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?	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, 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)?	Yes

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. (b) (6)

Attached Files

None

REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.CTP.V.V3
Report Category	Tobacco Product Report V3
Submitted	2019-04-03
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 SRP)?	No

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	<blank>
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	<blank>
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	06/20/2018
Problem End Date	04/03/2019
Please describe the health problem or product problem.	I have had multiple seizure like episodes as well as other neurological 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	(b) (6)

Age of the person when the problem occurred	23
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-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

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

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?	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/ 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?	<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>
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?	10
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, 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	(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?	Both (health problem that is also associated with a product problem or defect)

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

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 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 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	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 problem occurred	14
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-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	<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?	<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>
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)?	Unknown

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) [redacted]

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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?	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	<blank>
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)	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 pre-existing 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	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	Uses prefilled cartridge, cart, cartomizers or carto.

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	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, 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)?	No

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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 problem or product problem.	I believe vape smoking is the cause of my son's seizure. There is no 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 pre-existing health problems for the affected person	none1/

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	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)
Select all that apply to the e-liquid, 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)	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	000000000000
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?	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	<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?	<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?	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, 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)?	No

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

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

Contact Information - Sender

Organization Name	<blank>
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	(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, 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	01/28/2019
Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.	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 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	16
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	NO PRE-EXISTING ISSUES

Medications and Supplements

Please list the prescription medications, over-the-counter 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 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-liquid, 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 "UL" symbol?	Don't Know
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 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?	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, 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)?	No

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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	//2016
Problem End Date	//2019
Please describe the health problem or product problem.	I have been vaping for over 5 years but around two three years ago 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?	3
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
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 pre-existing 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

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 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
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 "UL" symbol?	No
Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)	None
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	Ohm vaper
Country	United States
Phone	<blank>
Street Address Line 1	<blank>
Street Address Line 2	<blank>
City/Town	<blank>
State	Florida
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?	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	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

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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	<blank>
Please describe the health problem or product problem.	I started smoking VUSE electronic cigarettes around April 2015 and I 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	(b) (6)

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 product (including electronic waterpipe)	Rechargeable product
Select all that apply to the e-liquid, 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 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?	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)?	No

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	(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 SRP)?	Yes
Describe who the problem was reported to	emergency room doctor and nurse, local.

Contact Information - Sender

Organization Name	<blank>
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	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 non-responsive. 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) [redacted]. 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) [redacted]
Age of the person when the problem occurred	18
Select Unit of Age	year(s)

Please list any known pre-existing 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	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 "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?	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)
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	(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 SRP)?	No

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 problems associated with a tobacco product?	Yes

Problem Summary

Problem Start Date	04/03/2019
Problem End Date	04/03/2019
Please describe the health problem or product problem.	on april 3rd i was in the tanning bed and got out and was really really 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	<blank>
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 pre-existing 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 e-liquid, 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	<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?	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?	5
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?	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	(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 SRP)?	No

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	<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	(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

Problem Start Date	01//2019
Problem End Date	<blank>
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 affected?	<blank>
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 pre-existing 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.	Lexipro

What are the main symptoms or health problems?

Term describing the health problem	Epilepsy

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")	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?	<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?	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	<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

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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?	No
Describe your relationship to the person who experienced the health problem	Mother

Problem Summary

Problem Start Date	04/26/2018
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 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 pre-existing 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 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)	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, 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)?	No

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	(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 SRP)?	<blank>

Contact Information - Sender

Organization Name	<blank>
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	(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

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 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 pre-existing 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	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 e-liquid, 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")	JUUL
When did the person purchase this product?	09/01/2018
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)	<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

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)?	Yes

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	(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 SRP)?	Yes
Describe who the problem was reported to	Vanderbilt University Children's hospital

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?	Yes
Job Title	(b) (6)
Phone	<blank>
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	Healthcare Professional (FdaTPR)
Healthcare Professional type	Other Public Health Professional
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	02/28/2019

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?	1
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	(b) (6)
Age of the person when the problem occurred	14
Select Unit of Age	year(s)
Please list any known pre-existing 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	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 e-liquid, 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 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?	20
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 product part?	<blank>

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	<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	<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)?	No

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

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

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) [redacted]
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 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	25
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	Polyglandular autoimmune disease type 2

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	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	<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?	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	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")	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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<blank>
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, Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	Yes

Problem Summary

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	(b) (6)
Age of the person when the problem occurred	44
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-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 "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?	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>

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?	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, 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)?	Yes

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.	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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	
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	<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 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	<blank>

Age of the person when the problem occurred	33
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-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)	Disposable (non-refillable) product, Rechargeable product, Button activated, Puff/flow activated
Select all that apply to the e-liquid, 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)	Other
Describe other e-liquid ingredients	Cannabis
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?	12/03/2018
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?	<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?	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>
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)?	No

Tobacco Product Parts

Other Products Used

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

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	2019-04-04
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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	
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)	Consumer
Are you the person who experienced health problems associated with a tobacco product?	Yes

Problem Summary

Problem Start Date	02/08/2018
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.	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	(b) (6)
Age of the person when the problem occurred	21
Select Unit of Age	year(s)
Please list any known pre-existing 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	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 prefilled cartridge, cart, cartomizers or carto.

Select all that apply to the e-liquid, 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	<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?	6
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)?	No

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 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?	Yes

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

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

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

Contact Information - Sender

Organization Name	<blank>
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	<blank>
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)	Consumer
Are you the person who experienced health problems associated with a tobacco product?	Yes

Problem Summary

Product Problem Type (select all that apply)	Label issue
Describe the other product problem	<blank>

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 information.	Seizures
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?	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	43
Select Unit of Age	year(s)
Please list any known pre-existing 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	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 e-liquid, 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?	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?	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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	<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	<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	02//2017
Problem End Date	02//2017
Please describe the health problem or product problem.	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	(b) (6)

Age of the person when the problem occurred	27
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-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 e-liquid, 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	<blank>
Street Address Line 1	<blank>
Street Address Line 2	<blank>
City/Town	Duluth
State	Minnesota
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?	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, 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)?	Yes

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	[redacted]
Followup by using your account	(b) (6) [redacted]

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) [redacted]
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

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6) [redacted]
First Name	[redacted]
Last Name	(b) (6) [redacted]
Did you report the problem to the manufacturer?	<blank>
Job Title	<blank>
Phone	[redacted]
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6) [redacted]
Country	United States
Street Address Line 1	(b) (6) [redacted]
Street Address Line 2	<blank>
City/Town	(b) (6) [redacted]
State	(b) (6) [redacted]
ZIP/Postal Code	[redacted]
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?	<blank>

Problem Summary

Problem Start Date	12/04/2018
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.	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 affected?	1
Gender	Male
Race (Select all that apply)	<blank>
Ethnicity	Not Hispanic or Latino

Birth date of the person who experienced the problem	[redacted]
Age of the person when the problem occurred	27
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	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.	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)	Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Puff/flow 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), 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	<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?	<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?	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, 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)?	Yes

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	
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)	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?	1
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	(b) (6)
Age of the person when the problem occurred	15
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	cleft palate ADHD 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.	concerta Lexapro intuiniv

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., Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user)

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	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

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?	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)?	No

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

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	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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	

Section A - About the Problem

	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	05-Aug-2016
	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)	Had a 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 had been vaping for months and just had a seizure. Went to neurologist and she confirmed that I did have a seizure but no epilepsy and never had a seizure before then and haven't had another one. Also, recently I changed flavors on my vape juice and ended up in emergency room with heart palpitations, and blood pressure issues. I stopped vaping after the ER visit and the symptoms and heart problems stopped instantly. M

Relevant 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	

	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		
	Type	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)	Vape		
	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	
	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			
	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

To help quit 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	(b) (6)
	Gender	Female
	Age (specify unit of time for age)	
	Date of Birth	(b) (6)
	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 (such as to drugs, foods, pollen or others)

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

Smoker

List all current prescription medications and medical devices being used.

atenolol 25mg

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

Women's one a day vitamin

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	[redacted]
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	03-Apr-2019	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.CTP.V.V3
Report Category	Tobacco Product Report V3
Submitted	2019-04-04
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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	<blank>
First Name	(b) (6)
Last Name	(b) (6)
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	<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 problem or product problem.	After smoking excess amount of tobacco products I would fall 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	(b) (6)

Age of the person when the problem occurred	21
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-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	Roll-your-own cigarette
Tobacco Product Subtype	<blank>
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/ 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?	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?	<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, 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 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	<blank>
State/Province	<blank>

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., 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 modified by the user? (select all that apply)	The tank system has been changed
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)	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?	<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 product?	No
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, 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	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 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?	<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	<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	[redacted]
Report Key for Followup	(b) (6) [redacted]

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) [redacted]
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

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	<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	(b) (6)
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	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 pre-existing 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

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 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), 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/ 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?	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 product?	No
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, 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)?	Yes

Other Tobacco Products

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

Organization Name	<blank>
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	
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)	Consumer
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	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 pre-existing 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 e-liquid, 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 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	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	[redacted]
Followup by using your account	(b) (6) [redacted]

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) [redacted]
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

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)
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

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.
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?	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	<blank>
Birth date of the person who experienced the problem	(b) (6)
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	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.	<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/ 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	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?	<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?	No
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)?	Unknown

Tobacco Product Parts

Other Products Used

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

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	[redacted]
Followup by using your account	(b) (6) [redacted]

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) [redacted]
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

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?	<blank>
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	<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?	No
Describe your relationship to the person who experienced the health problem	Mother

Problem Summary

Problem Start Date	04/02/2019
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 daughter took a puff off of a Juul brand e cigarette and within a few 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 drive for 3 months.
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?	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	(b) (6)
Age of the person when the problem occurred	18
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	No 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.	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

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	Disposable (non-refillable) product

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	<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 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?	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?	<blank>
Select Unit of Measure	<blank>
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?	<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 (either currently or in the past)?	No

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	<blank>
Street Address Line 1	(b) (6)
Street Address Line 2	(b) (6)
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, Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	Yes

Problem Summary

Problem Start Date	12/01/2018
Problem End Date	12/19/2018
Please describe the health problem or product problem.	I was using a Suorin Air. A nicotine device just as I normally have for 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 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?	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	Male
Race (Select all that apply)	White
Ethnicity	<blank>
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 pre-existing 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 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), 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/ batch code)	<blank>
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?	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 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?	30
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, 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	[redacted]
Followup by using your account	(b) (6) [redacted]

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)?	<blank>

Contact Information - Sender

Organization Name	<blank>
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 Minor Outlying Islands
Street Address Line 1	(b) (6)
Street Address Line 2	<blank>
City/Town	(b) (6)
State/Province	(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?	Yes

Problem Summary

Problem Start Date	02/01/2017
Problem End Date	<blank>
Please describe the health problem or product problem.	I STARTED USING E-CIG PRODUCTS ABOUT 5 YEARS AGO. 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	2
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-the-counter 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 e-liquid, 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?	<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?	<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?	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	(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 SRP)?	No

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 apply)	Concerned citizen
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	<blank>
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 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 pre-existing health problems for the affected person	ADHD

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>
Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)	<blank>
Select all that apply to the e-liquid, 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)	<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")	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/ 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?	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	<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?	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)?	Unknown

Tobacco Product Parts

Other Products Used

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

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?	<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	2019-04-05
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 SRP)?	No

Contact Information - Sender

Sender Category	Consumer/Concerned Citizen (FdaTPR)

Problem Summary

Problem Start Date	12/25/2018
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.	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 separate report for each affected person, if possible.)	User(s)
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	(b) (6)
Age of the person when the problem occurred	18
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-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)	Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto., Puff/flow 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)	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?	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/ 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?	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>
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?	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	(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 SRP)?	No

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?	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	(b) (6)
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	17
Select Unit of Age	year(s)
Please list any known pre-existing 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.	Blivosi (birth control pill), Advil

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-liquid, e-juice or vape juice (purchased separately)
Select all that apply to the e-liquid, e-juice or vape juice	Purchased in a non-refillable disposable 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")	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?	<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?	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?	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)?	Unknown

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

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	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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	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	12-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)	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	

	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)	Yes

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)	JUUL		
	Name of the company that makes (or compounds) the product	JUUL		
	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?			

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		
	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	(b) (6)
	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)

Seizure Disorder

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.)

I smoke juul, and my daughter had been exposed two second-hand smoking.

List all current prescription medications and medical devices being used.

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

Section F - About the Person Filling Out This Form 1 of 1

Primary?	(b) (6)
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	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):	No	


JUUL
the alternative for adult smokers
JUUL device
USB charger
4 pod multipack
5% strength

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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	<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	<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 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 pre-existing 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.	<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 "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?	<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?	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?	No
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)?	No

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	2019-04-05
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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	<blank>
First Name	(b) (6)
Last Name	(b) (6)
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	<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	Mother

Problem Summary

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?	1
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 pre-existing health problems for the affected person	NA

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	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

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?	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

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	04-Apr-2019	CTU Received Date	05-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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	10-Feb-2017
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)

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)

My son had a seizure after vaping an e-cig. Brand:JULE Age:15

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

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)	JULE		
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	
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?	Doesn't Apply		

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	11-Oct-2016		
Date the person stopped taking or using the product	10-Mar-2018		
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	(b) (6)
	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)

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.

Briviact

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

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	
Country	(b) (6)
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	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):	No	

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	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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	14-Sep-2018
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)	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)

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. (b) (6)

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date		
Test Result		Test Unit		
Low Test Range		High Test Range		
More Information Available?				

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	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)	Juele		
Name of the company that makes (or compounds) the product	Vap		
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?	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		If Other		
	Date the person first started taking or using the product	14-Sep-2018			
	Date the person stopped taking or using the product	22-Oct-2018			
	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	(b) (6)
	Gender	Male
	Age (specify unit of time for age)	17 Year(s)
	Date of Birth	
	Weight	63 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)

none

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

none

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

none

List all current prescription medications and medical devices being used.

none

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	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	

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	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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	X	X		

Section A - About the Problem

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	15-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)

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)

Two separate incidences of seizures occurred. Experienced by my younger brother (21 years old). Heavy user of e-cigarettes, specifically JUUL. Medically unconfirmed cause of seizures. Both incidences required hospitalization. Reporting as a member of the health field wanting to help the FDA with it's research about the possible link between e-cigarettes and seizures. Thank you.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

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)	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 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?	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	
	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		

	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 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	Unspecified
	Gender	Male
	Age (specify unit of time for age)	21 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)

migraines, anxiety	

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.)

alcohol use	

List all current prescription medications and medical devices being used.

gabapentin for migraines, anti-anxiety medication	

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

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	X
Middle Name	
First name	X
Number/Street	
City	
State/Province	
Country	USA
ZIP or Postal code	
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	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	

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	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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	

Section A - About the Problem

	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	
	Serious	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)

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)

Two different times, I had a mild seizure after I used a Juul. I've never had a seizure before in my life.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

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)	Juul		
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	
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			
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

	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	(b) (6)
	Gender	Female
	Age (specify unit of time for age)	20 Year(s)
	Date of Birth	
	Weight	65.25 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)

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

Amoxicillin, Sulfa

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.

Zoloft

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

Vitamin D, Iron

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	(b) (6)
Number/Street	
City	
State/Province	
Country	USA
ZIP or Postal code	
Telephone number	
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	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):	No	

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	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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	17-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)

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 seizures to the point of breaking my hand. The seizures are getting worse and it is hard to stop using product.

Relevant 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?			

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)	Juul		
Name of the company that makes (or compounds) the product	Juul		
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?	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			

	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	(b) (6)
	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)

Seizures and bipolar

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

Trazadone cipro

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.

Lexapro keppra abilify

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

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	04-Apr-2019	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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	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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	10-Nov-2018
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)

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)

My 17 year old son who's been using/addicted to vaping with Juul pods since Freshman year of high school had seizure. Was hospitalized for nicotine and drug addiction and has been to rehab twice since. We have never seen so many young people vaping - even as young as middle school age. My son is still addicted to nicotine and has needed the patch and gum to stop. He has also started smoking cigarettes. Completely against the marketing messages from Juul and other companies saying how less harmful they are. This is an Epidemic for our young people and is a starting point for other drugs. This needs to be researched especially when dealing with the adolescent growing brain.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

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)	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 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?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

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			
Date the person stopped taking or using the product			
Give best estimate of duration	2 Year		

	Is therapy still on-going?	Yes

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Recreational

	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	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)

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.)

Minor under age of 18

List all current prescription medications and medical devices being used.

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

Section 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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	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	

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	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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	25-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)

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)

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.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

I believe the product is still in the possession of (b) (6) [redacted]

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			
	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 it 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?			

Drug Therapy 1 of 1

	Expiration date			
	Lot number	Unknown		
	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	
	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	(b) (6)
	Gender	Female
	Age (specify unit of time for age)	15 Year(s)
	Date of Birth	
	Weight	49.5 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)

Anxiety. Otherwise healthy, fit.

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

Pollen

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.

300 mg Wellbutrin. Since incident, stopped taking.

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

Benadryl, Zyertec

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	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	

MedWatch 3500B Consumer/Patient Report

The FDA Safety Information and Adverse Event Reporting Program

FDA Safety Report ID #	(b) (6)	FDA Received Date	03-Apr-2019

SECTION A - ABOUT THE PROBLEM			
A1. What kind of problem was it?	Were hurt or had a bad side effect *(including new or worsening symptoms)*	Yes	
	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		
A2. Did any of the following happen?	Hospitalization - admitted or stayed longer	Yes	
	Required help to prevent permanent harm		
	Disability or health problem	Yes	
	Birth defect		
	Life-threatening		
	Death *(include date)*		
	Other serious/important medical incidents *(please describe)*	Yes	Grand mal seizures
A3. Date the problem occurred:	09-Mar-2016		

A4. Tell us what happened and how it happened:

I have had five grand mal seizures and will be seeing my neurologist within the next few weeks to discuss another two situations that seizures may have occurred. I am assuming that these two instances are seizures with one not being a grand mal seizure (my assumption is based off of my own research from online websites that I think are credible). I am contacting you because I saw a news article about the relations between e-cigarettes and seizures. I graduated high school in 2016 and had used e-cigarettes during late high school. I have gotten multiple EEGs done with all being normal besides the one in which I stayed in the hospital. The staff told me that I have genetic epilepsy but nobody in my family or extended family has epilepsy or has had a seizure. I received this information from someone who exams EEGs (waves if you will) that works with my neurologist. From the same person, I was told that I had 20 spike in my EEG during the day that I stayed in the hospital. She explained it to me as sparks that can cause a fire/seizure. From what I can remember, she also said that most of these spikes happened when I was sleeping.

A5. Relevant Tests/Laboratory Data:	
Test 1	
Test Date:	12-Oct-2018
Test Name:	EEG
Test Result:	Genetic epilepsy
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:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 4	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

A5. Relevant Tests/Laboratory Data:	
Test 5	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 6	
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	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

A5. Additional Comments:		
Please select the cause of the problem that applies below:	Problem with a product	Yes
	Problem with a device	Yes

SECTION B - PRODUCT AVAILABILITY	
B1. Do you still have the product in case we need to evaluate it?	No
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	
C3. Check if therapy is on-going		
C4. Name(s) of the company that makes (or compounds) the product:		
C5. Product Type:	OTC (Over-the-counter)	
	Compounded	Yes
	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:		
C5. Product Type:	OTC (Over-the-counter)	
	Compounded	
	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?		

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	
D9. If yes, who was operating it?	The person who had the problem	
	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 THE PROBLEM		
E1. Person's Initials:	NRF	
E2. Gender:	Female	
	Male	Yes
	Intersex	
	Transgender	
	Prefer not to disclose	
E3. Age:		
E4. Date of Birth:	(b) (6)	
E5. Weight:	140	lb
E6. Ethnicity:	Hispanic/Latino	
	Not Hispanic/Latino	Yes
E7. Race:	Asian	
	American Indian or Alaskan Native	
	Black or African American	
	White	Yes
	Native Hawaiian or Other Pacific Islander	

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

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 FORM	
F1. Last Name	(b) (6)
F2. First Name	(b) (6)
F3. Number/Street	(b) (6)
F4. City and State/Province	(b) (6)
F5. ZIP or Postal Code	(b) (6)
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

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	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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	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	26-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)	Increase in seizure activity

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)

In relation to the link between vaping and seizures, I was diagnosed with epilepsy in 2007 and recently have vaping coworkers in the office who openly vape throughout the day. Having surgery to correct my condition I seemed to be seizure free until recently. Our office atmosphere is consistently full of vape smoke. I do have a concern, as this will have a detrimental effect on my career.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes		
	Primary?	Yes		
	Type	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 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?	No		
	Did the problem return if the person started taking or using the product again?			

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		
	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	(b) (6)
	Gender	Male
	Age (specify unit of time for age)	42 Year(s)
	Date of Birth	
	Weight	98.55 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)

	Epilepsy

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

	None

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.

	Trileptal, oxcarbazipene, lamotrigene, briviact

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

	B-12

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	(b) (6)
	Number/Street	(b) (6) ,
	City	(b) (6)
	State/Province	(b) (6)
	Country	USA
	ZIP or Postal code	(b) (6)
	Telephone number	(b) (6)
	Email address	(b) (6)
	Fax	
	Reporter Organization	
	Department	
	Reporter Speciality	

	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	

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	
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 problem or product problem.	My son had to separate seizures on two separate incidents after vaping 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 or more)	Life threatening
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?	2
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)	<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 pre-existing health problems for the affected person	Type 1 diabetes, 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.	Insulin

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")	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?	<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?	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>
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)?	<blank>

Tobacco Product Parts

Other Products Used

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

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	<blank>
Street Address Line 2	<blank>
City/Town	<blank>
State	(b) (6)
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	11/26/2017
Problem End Date	<blank>
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?	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	22
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	Hypothyroidism

Medications and Supplements

Please list the prescription medications, over-the-counter 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 product (including electronic waterpipe)	Rechargeable product
Select all that apply to the e-liquid, 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)
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?	2
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

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?	No

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	<blank>
State/Province	<blank>

Other Products Used

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

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	(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 SRP)?	No

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	(b) (6)
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 problem or product problem.	Had a seizure 4/1/19 around 8am lasted two minutes long. Started 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 pre-existing 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 waterpipe)	<blank>
Select all that apply to the e-liquid, 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)	<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")	Smok Nord with 25mg nicotine levels pachy mama liquid
When did the person purchase this product?	09/01/2018
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?	China
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?	7
Select Unit of Measure	Month(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?	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, 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)?	Yes

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	(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 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 anti-seizure 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	(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)
State	(b) (6)
ZIP/Postal Code	(b) (6)
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?	2
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	(b) (6)
Age of the person when the problem occurred	18
Select Unit of Age	year(s)
Please list any known pre-existing 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 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 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)	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/ 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	Vape store
Country	United States
Phone	<blank>
Street Address Line 1	<blank>
Street Address Line 2	<blank>
City/Town	<blank>
State	Colorado
ZIP/Postal Code	81507
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?	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?	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

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(b) (6)
Street Address Line 2	(b) (6)
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 pre-existing health problems for the affected person	Epilepsy

Medications and Supplements

Please list the prescription medications, over-the-counter 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 "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?	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 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
Describe what substances are being mixed with the tobacco product	<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	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, 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)?	Yes

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	(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 SRP)?	No

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?	<blank>
Job Title	<blank>
Phone	<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	<blank>
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	<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 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	(b) (6)
Age of the person when the problem occurred	<blank>
Select Unit of Age	<blank>
Please list any known pre-existing health problems for the affected person	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 product (including electronic waterpipe)	<blank>
Select all that apply to the e-liquid, 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?	<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>

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. Urine tox was consistent with just marijuana and nicotine.
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?	<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)?	<blank>

Tobacco Product Parts

Other Products Used

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

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<blank>
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	(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?	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 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.	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?	20
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	(b) (6)
Age of the person when the problem occurred	14
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	no known

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-liquid, e-juice or vape juice (purchased separately)
Select all that apply to the e-liquid, 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 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 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	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?	Unknown
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

Other Tobacco Products

Additional Information

Attached Files

None

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	05-Apr-2019	CTU Received Date	05-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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	15-Jul-2013
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)	

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)

Possible seizure do to ECIG Had recently started using ECIG. Had no history of seizure. On freeway driving a vehicle. Partner was with me I started to having seizure luckily partner was there with me to take over the vehicle. I also experienced lots of out of character behavior. Lots of psychiatric problems. I did report to my Dr. Webber. I have had problems to this day. Don't know why. I was living in (b) (6) MN at the time.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	

	Low Test Range		High Test Range		
	More Information Available?				

Additional Comments

ECIG and Vapor. No stopped vaping a long time ago.

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	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)	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 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?				

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	
	Is therapy still on-going?	Yes

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	(b) (6)
	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

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.

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	05-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	

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 submitting?	Both (health problem that is also associated with a product problem or defect)

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

Contact Information - Sender

Organization Name	<blank>
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	<blank>
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?	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
Ethnicity	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 pre-existing health problems for the affected person	Peanut and Tree Nut allergy

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	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)	<blank>
Select all that apply to the e-liquid, 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?	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 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?	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?	<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?	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)?	Unknown

Tobacco Product Parts

Other Products Used

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

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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?	No
Describe your relationship to the person who experienced the health problem	Father of person who experineced the problem

Problem Summary

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 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.	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?	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)	<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 pre-existing 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	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 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)	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	<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?	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?	<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, 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)?	No

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	(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 SRP)?	No

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?	<blank>
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	(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	02/01/2018
Problem End Date	04/08/2019
Please describe the health problem or product problem.	I began vaping a about a year ago, and one day after I had been vaping 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?	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 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 pre-existing health problems for the affected person	no pre existing 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

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 e-liquid, 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 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?	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, 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)?	No

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	2019-04-08
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 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

Contact Information - Sender

Organization Name	<blank>
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	(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?	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?	7
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
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	(b) (6)
Age of the person when the problem occurred	20
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	History of 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.	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 e-liquid, 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 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?	<blank>
Select Unit of Measure	<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, 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)?	Yes

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	(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 SRP)?	Yes
Describe who the problem was reported to	my general physician and doctors at the hospital

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?	<blank>
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 problems associated with a tobacco product?	Yes

Problem Summary

Problem Start Date	<blank>
Problem End Date	<blank>
Please describe the health problem or product problem.	experienced syncope or seizure while using tobacco vapor product that 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. I also got an MRI of the brain that came back normal. and a heart ultrasound thst 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 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 pre-existing health problems for the affected person	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.	<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 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), 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	<blank>
Street Address Line 1	<blank>
Street Address Line 2	<blank>
City/Town	roseville
State	Michigan
ZIP/Postal Code	48066
Web Address	<blank>
Email Address	<blank>

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	<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?	<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
Select Unit of Measure	Minute(s)
How long has the person been using this particular brand or label?	1
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, 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)?	<blank>

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	2019-04-09
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 SRP)?	No

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?	<blank>
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, Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	<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?	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	25
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-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 prefilled cartridge, cart, cartomizers or carto., Puff/flow activated
Select all that apply to the e-liquid, 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 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	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, 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)?	Yes

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	(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 SRP)?	No

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	<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)	<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 problem	<blank>

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.	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?	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 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 pre-existing 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	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	Rechargeable product, Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user), Uses a tank or tank system, Puff/flow activated

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	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 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?	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?	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

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

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>

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

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	08-Apr-2019	CTU Received Date	08-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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)		

Section A - About the Problem

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	
Serious	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)

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)

Reoccurring issue has occurred with me when using juul. I have had a tremor problem worsen over the year and juuling causes my tremors to sometimes worsen dramatically and affect other areas of my body.

Relevant 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?			

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		
	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)	Juul		
	Name of the company that makes (or compounds) the product	Juul		
	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?	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	
	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		

	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Recreational

	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	(b) (6)
	Gender	Male
	Age (specify unit of time for age)	18 Year(s)
	Date of Birth	
	Weight	56.25 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)

	Dépression/anxiety

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.

	Zoloft

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

	Vitamin D

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	(b) (6)
	Number/Street	
	City	
	State/Province	--
	Country	USA
	ZIP or Postal code	
	Telephone number	
	Email address	
	Fax	
	Reporter Organization	
	Department	
	Reporter Speciality	

	Today's date	08-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	

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	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		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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/Laboratory Data 1 of 1

Test Name	BRAIN MAGNETIC RESSONANCE	Test Date	31-Mar-2019
Test Result	Nothing was identified	Test Unit	PERCENT

	Low Test Range		High Test Range		
	More Information Available?				

Additional Comments

	No abnormal results

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			
	Type	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)	Juul with 5% nicotine juul pods			
	Name of the company that makes (or compounds) the product	Juul			
	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?	Yes			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			

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	01-Nov-2018			

	Date the person stopped taking or using the product	30-Mar-2019
	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

Started to use Juul in attemp to quit 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	(b) (6)
	Gender	Male
	Age (specify unit of time for age)	
	Date of Birth	(b) (6)
	Weight	67 kg
	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)

No medical conditions

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

Allergic to peniciline only

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

N/a

List all current prescription medications and medical devices being used.

Lyrica to diminish risks of additional seizure events

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

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	
Country	(b) (6)
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	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	

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	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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)		

Section A - About the Problem

	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	
	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)	Seizures

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)

When I was vaping i started having seizures. It started as just one but it has been 2 years now and I have had at least 4-5+ now. I was vaping with one of them mechanical mods and had 1.5milligram nicotine. Also while vaping I noticed it made my heart start beating noticeably irregular.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

It has been 4 years since I quit vaping. I still have irregular heart beats and most recent seizure was about two months ago.

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		
	Type	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	
	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		

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	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 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
	Age (specify unit of time for age)	23 Year(s)
	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)

	Past heart issue known as SVT

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

	None

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

List all current prescription medications and medical devices being used.

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

Section 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	(b) (6)
	Number/Street	
	City	
	State/Province	--
	Country	USA
	ZIP or Postal code	
	Telephone number	
	Email address	
	Fax	
	Reporter Organization	
	Department	
	Reporter Speciality	

	Today's date	03-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	

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	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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	

Section A - About the Problem

	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	23-Oct-2013
	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)	Seizures

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)

After seeing the information released today about a possible link between vaping and seizures I thought I should report it. I started having seizures suddenly out of nowhere and have been diagnosed epileptic. I have had many tests and no cause has been found. I started using e cigarettes approximately 2 weeks prior to them beginning. I was a heavy smoker at the time but I dont know if the change to the liquid form would have made that much of an impact. I am currently a vaper at the moment.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

	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		
	Type	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)	Nicotine e cigarettes		
	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	
	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?			

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		
	Is therapy still on-going?	Yes	

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	[redacted]
	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)

Epilepsy

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.)

E cigarette user

List all current prescription medications and medical devices being used.

Keppra, zonagren, lamictal

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

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	03-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	

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	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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	01-Jul-2014
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)

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 stopped smoking regular cigarettes and started using vape cigarettes I began to have seizures shortly after. I had never had seizures prior to that.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date		
Test Result		Test Unit		
Low Test Range		High Test Range		
More Information Available?				

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)	Vuse Solo		
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	
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		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		
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	(b) (6)
	Gender	Female
	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)

	Seizures

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

	None

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.

	Keppra

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

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	(b) (6)
	Number/Street	(b) (6)
	City	(b) (6)
	State/Province	(b) (6)
	Country	USA
	ZIP or Postal code	(b) (6)
	Telephone number	(b) (6)
	Email address	(b) (6)
	Fax	
	Reporter Organization	
	Department	
	Reporter Speciality	

	Today's date	03-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	

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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	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	11-Jan-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)	Seizures

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)

Have smoked ecigs for 5 years recently started to have siezuires

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

	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		
	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)	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 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?	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	
	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		
	Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Quit 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	Dkb
	Gender	Male
	Age (specify unit of time for age)	30 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

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

Seizures	

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

Amoxicillin	

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

Smoking e-cigarettes	

List all current prescription medications and medical devices being used.

Gabbapentin	

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

Advil	

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	(b) (6)
Number/Street	(b) (6)
City	
State/Province	[redacted]
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
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	

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	(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 SRP)?	No

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	<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>
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	03/28/2019
Problem End Date	03/30/2019
Please describe the health problem or product problem.	Seizure from SALT vapor juice that was not told to me that you can not 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 or more)	Life threatening
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?	7
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	47
Select Unit of Age	year(s)

Please list any known pre-existing health problems for the affected person	Bipolar 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.	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 e-liquid, 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), Other
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	<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?	<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?	4

Select Unit of Measure	Day(s)
How soon after the tobacco product was last used did the problem occur?	30
Select Unit of Measure	Second(s)
How long has the person been using this particular brand or label?	4
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, 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)?	Yes

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

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	11-Apr-2019	CTU Received Date	11-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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)		

Section A - About the Problem

	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	10-Jan-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)	Seizures

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)

My 16 yr old daughter had a print stick MOD vape of nicotine at school less then 5 minutes later she had a full seizure and was unconscious and had an ambulance called. She came to with high blood pressure,anxiety and no recollection of the incident and was taken to the hospital for tests ,all came back ok and we were told is was most likely from her vaping

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	10-Jan-2019
	Test Result		Test Unit	
	Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

My 16 year old daughter had a vape of nicotine at school and 5 minutes later hit the ground in a full seizure. She was unconscious and an ambulance was called. She came to with no recollection of the incident, high blood pressure and horrible anxiety, she has no medical conditions and was cleared at the hospital of any other issues.. it took her a long time to calm down after the seizure

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			
	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 Pharmacy or an Outsourcing Facility ☑ Generic ☐ Biosimilar		
	Strength	Other	If Other	50 of nicotine vap
	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		

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			
	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

	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	[redacted]
	Gender	Female
	Age (specify unit of time for age)	16 Year(s)
	Date of Birth	
	Weight	49.5 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)

NA

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

NA

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.

None

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	(b) (6)
Number/Street	[redacted]
City	
State/Province	(b) (6)
Country	(b) (6)
ZIP or Postal code	
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	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	

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	11-Apr-2019	CTU Received Date	11-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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	
Serious	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)

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)

Not sure of the exact date but sometime around Nov.2018 I had the first of 3 mild seizures I believe from vaping. I am 55 years old and never had one until then. It was mild and only lasted a few seconds but I felt like my brain misfired. It was as if time stopped for a few seconds. My hearing became fuzzy, my eyes dazed and then I felt like I woke up and was okay at that point. I was vaping 18 mg at that time and have since lowered to 12 mg and have not had that occur again since then. The device I was using is a Smok Alien 220W and I was vaping MBYC 18mg that I purchased from www.gaintvapes.com I did not seek medical attention due to this but told my boyfriend about it so he could keep an eye on me in case I did end up needing medical assistance.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date		
Test Result		Test Unit		
Low Test Range		High Test Range		

	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		
	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)	MBYC Vapor		
	Name of the company that makes (or compounds) the product	Purchased from www.gaintvapes. com		
	Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
	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		

Drug Therapy 1 of 1

	Expiration date			
	Lot number			
	Dosage Form			
	Quantity		If Other	
	Frequency	As needed	If Other	
	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 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

alternative to 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	[redacted]
	Gender	Female
	Age (specify unit of time for age)	55 Year(s)
	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

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

none

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.

Rosuvastatin calcium 5 mg and Levothyroxine 150 MCG Vitamin D3 2,000

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

Rosuvastatin calcium 5 mg and Levothyroxine 150 MCG Vitamin D3 2,000

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	(b) (6)
Number/Street	(b) (6) ---
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	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	

MedWatch 3500 Health Professional Report

The FDA Safety Information and Adverse Event Reporting Program

FDA Safety Report ID #	(b)(6)	FDA Received Date	11-Apr-2019

A. PATIENT INFORMATION		
A1. Patient Identifier:	[redacted]	
A2. Age:	16	Year(s)
A2. Date of Birth:		
A3. Gender:	Female	
	Male	Yes
	Intersex	
	Transgender	
	Prefer not to disclose	
A4. Weight:	65	kg
A5. Ethnicity:	Hispanic/Latino	
	Not Hispanic/Latino	Yes
A6. Race:	Asian	
	American Indian or Alaskan Native	
	Black or African American	Yes
	White	
	Native Hawaiian or Other Pacific Islander	

B. ADVERSE EVENT, PRODUCT PROBLEM		
B1. Type of Report:	Adverse Event	Yes
	Product Use/Medication Error	
	Product Problem (e.g., defects/malfunctions)	
	Problem with Different Manufacturer of Same Medicine	
B2. Outcome Attributed to Adverse Event:	Death *(Date of Death)*	
	Life-threatening	
	Hospitalization (initial or prolonged)	
	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	

B5. Describe Event, Problem or Product Use/Medication Error:

Teenage young man with epilepsy, on medication, experienced breakthrough seizures on 3/23/19 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 preventative medication.

B6. Relevant Tests/Laboratory Data:	
Test 1	
Test Date:	
Test Name:	
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:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 4	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

B6. Relevant Tests/Laboratory Data:	
Test 5	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 6	
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	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

B6. Additional Comments:

normal labs at time of seizure, except glucose slightly elevated as expected

B7. Other Relevant History, Including Preexisting Medical Conditions:

Primary generalized epilepsy

C. PRODUCT AVAILABILITY	
C1. Product Available for Evaluation?	No
C1. Returned to Manufacturer on:	
C2. Do you have a picture of the product?	

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)			
D1. Strength:	one	DF		
D1. Manufacturer/Compounder:	Juul			
D1. NDC # or Unique ID:	unknown			
D1. Lot #:				
D2. Dose or Amount:				
D2. Frequency:				
D2. Route:				
D3. Treatment Dates/Therapy Dates:	Start	23-Mar-2019	Stop	11-Apr-2019
	Give best estimate of duration			
	Is therapy still on-going?			
D4. Diagnosis for Use:				
D5. Product Type:	OTC (Over-the-counter)			
	Compounded			
	Generic			
	Biosimilar			
D6. Expiration Date:				
D7. Event Abated After Use Stopped or Dose Reduced?	Yes			
D8. Event Reappeared After Reintroduction?	Yes			
Product 2				
D1. Does this report involve cosmetic, dietary supplement or food/medical food?				
D1. Name:				
D1. Strength:				
D1. Manufacturer/Compounder:				
D1. NDC # or Unique ID:				
D1. Lot #:				
D2. Dose or Amount:				
D2. Frequency:				
D2. Route:				
D3. Treatment Dates/Therapy Dates:	Start		Stop	
	Give best estimate of duration			
	Is therapy still on-going?			
D4. Diagnosis for Use:				
D5. Product Type:	OTC (Over-the-counter)			
	Compounded			
	Generic			
	Biosimilar			
D6. Expiration Date:				
D7. Event Abated After Use Stopped or Dose Reduced?				
D8. Event Reappeared After Reintroduction?				

E. SUSPECT MEDICAL DEVICE			
E1. Brand Name:			
E2a. Common Device Name:	Juul		
E2b. Procode:			
E3. Manufacturer Name, City and State:			
E4. Model #:			
E4. Catalog #:			
E4. Serial #:			
E4. Lot #:			
E4. Expiration Date:			
E4. Unique Identifier (UDI) #:			
E5. Operator of Device:	Health Professional		
	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?			

F. OTHER (CONCOMITANT) MEDICA[redacted]UCTS

Product Name	Therapy Start Date	Therapy End Date
1. Keppra	04-Mar-2019	11-Apr-2019
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		
19.		
20.		
21.		

G. REPORTER		
G1. Name and Address	Last Name	(b) (6)
	First Name	(b) (6)
	Address	(b) (6)
	City	(b) (6)
	State/Province/Region	
	ZIP/Postal Code	(b) (6)
	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	
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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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?	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 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?	2
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	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	17
Select Unit of Age	year(s)

Please list any known pre-existing 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.	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)	Rechargeable product, Uses a tank or tank system
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	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 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?	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 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?	5
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, 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")	SuorinUSA Air V2 Ultra-portable system
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 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)?	Unknown

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<blank>
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	(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?	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 information.	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)	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	(b) (6)
Age of the person when the problem occurred	16
Select Unit of Age	year(s)
Please list any known pre-existing 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	Epilepsy 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	Disposable (non-refillable) product, Rechargeable product, Uses prefilled cartridge, cart, cartomizers or carto.

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	<blank>
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 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	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, 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)?	No

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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)	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, (b) (6) 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 (b) (6) 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 pre-existing health problems for the affected person	(b) (6) 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 product (including electronic waterpipe)	<blank>
Select all that apply to the e-liquid, 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>
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)?	Unknown

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 Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
04/15/2019	NYK-DO	SAN-DO	Telephone	Friend/Relative of Consumer	Allen,Vera L	Pending at Branch

Complainant Identification

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

Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
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.	Life Threatening Injury/Illness	02/17/2019	Seizures

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	04/15/2019	Yes	No	No	Not Reported to Manufacturer	

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)

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 Consumer Use	96R801	UNK

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
1 Count Other, identify in Label Remarks	UNK	N/A	2018	Yes	UNK

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
2018 - 04/2019	04/2019	NONE	No	United States	Packaging discarded. Product codes not available

Retail

Name	Address

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3013660768	Juul Labs, Inc. 560 20th St San Francisco California United States 94107-4344	SAN-DO	Corporate Headquarters

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

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 Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type

Follow-Up Disposition **Disposition Made By** **Disposition Date**

Disposition Remarks

Follow-Up Sent To

Organization Name **HHS Mail Code**

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	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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	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	10-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)	I had a 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 had a seizure the morning after a night of vaping. I had one a year ago after the same but at that time I didn't believe it was a seizure. I believe now that it was and I believe it was from vaping more than my normal (small) amount.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

	More Information Available?	

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	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)	Juul		
	Name of the company that makes (or compounds) the product	Juul		
	Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
	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		

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		
	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	(b) (6)
	Gender	Female
	Age (specify unit of time for age)	45 Year(s)
	Date of Birth	
	Weight	96.3 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)
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

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b)(6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	17-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	

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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?	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	(b) (6)
Age of the person when the problem occurred	29
Select Unit of Age	year(s)

Please list any known pre-existing health problems for the affected person	Epilepsy - (b) (6) has epilepsy, but it is very well controlled with 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.	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 or vaping product subtype	Juul Cool Mint
Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)	Uses prefilled cartridge, cart, cartomizers or carto.
Select all that apply to the e-liquid, 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), 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 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	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, 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
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	(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?	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	year(s)
Please list any known pre-existing 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.	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 e-liquid, 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 "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	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	<blank>
State	<blank>
ZIP/Postal Code	<blank>
Web Address	<blank>
Email Address	<blank>

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?	Yes
Describe what substances are being mixed with the tobacco product	Alcohol, 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?	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?	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)?	Yes

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	(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 SRP)?	No
Describe who the problem was reported to	<blank>

Contact Information - Sender

Organization Name	<blank>
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	(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?	No
Describe your relationship to the person who experienced the health problem	Father

Problem Summary

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 (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?	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	18
Select Unit of Age	year(s)
Please list any known pre-existing 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	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 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
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 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?	5
Select Unit of Measure	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, 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)?	Yes

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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	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) (6)

Age of the person when the problem occurred	58
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	High blood pressure, controlled by a doctor prescribed med.

Medications and Supplements

Please list the prescription medications, over-the-counter 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 product (including electronic waterpipe)	Puff/flow activated
Select all that apply to the e-liquid, 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 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?	10/15/2012
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)	I do not have the product any longer, as I haven't vaped since January/ Febuary 2013.
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	Liquivape
Country	United States
Phone	<blank>
Street Address Line 1	1214 Tower Ave.
Street Address Line 2	<blank>
City/Town	Superior
State	Wisconsin
ZIP/Postal Code	54880
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?	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, 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)?	Yes

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	<blank>
Street Address Line 2	<blank>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
Sender Category	Healthcare Professional (FdaTPR)
Healthcare Professional type	Nurse
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	(b) (6)

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 e-cigarette 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?	1
Select Unit of Time	minute(s)
What is the current status of the health problem?	Recovered or Resolved

Affected Person

Affected Person Identifier Code	JV
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	17
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	PTSD, Anxiety, Depression

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

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 product (including electronic waterpipe)	<blank>
Select all that apply to the e-liquid, 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/ batch code)	Student borrowed from a friend - unknown
What is the country of manufacture of the tobacco product?	<blank>
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 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?	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?	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 (either currently or in the past)?	Unknown

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 #	(b) (6)	FDA Received Date	26-Apr-2019

SECTION A - ABOUT THE PROBLEM			
A1. What kind of problem was it?	Were hurt or had a bad side effect *(including new or worsening symptoms)*	Yes	
	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		
A2. Did any of the following happen?	Hospitalization - admitted or stayed longer	Yes	
	Required help to prevent permanent harm		
	Disability or health problem		
	Birth defect		
	Life-threatening		
	Death *(include date)*		
	Other serious/important medical incidents *(please describe)*	Yes	Seizures.2
A3. Date the problem occurred:	25-Apr-2019		

A4. Tell us what happened and how it happened:

This is the second seizure experienced by my 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 E/Cigs. Both times rushed to hospital ER in Ridgewood NJ .. both times only results after barrage of tests were low potassium level.. He is addicted to this vapor and both times occurred after not vaping for a day.

A5. Relevant Tests/Laboratory Data:	
Test 1	
Test Date:	25-Apr-2019
Test Name:	CAT Scan
Test Result:	Negative
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:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 4	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

A5. Relevant Tests/Laboratory Data:	
Test 5	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 6	
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	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

A5. Additional Comments:		
Many tests were taken both ER visits.. we have all results.		
Please select the cause of the problem that applies below:	Problem with a product	
	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:		
C5. Product Type:	OTC (Over-the-counter)	
	Compounded	
	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?		

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		
C5. Product Type:	OTC (Over-the-counter)	
	Compounded	
	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?		

SECTION D - ABOUT THE MEDICAL DEVICE		
D1. Name of medical device:	E-Cig	
D2. Name of the company that makes the medical device:		
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?		
D9. If yes, who was operating it?	The person who had the problem	
	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 THE PROBLEM		
E1. Person's Initials:	MAN	
E2. Gender:	Female	
	Male	Yes
	Intersex	
	Transgender	
	Prefer not to disclose	
E3. Age:		
E4. Date of Birth:	(b) (6)	
E5. Weight:	180	lb
E6. Ethnicity:	Hispanic/Latino	
	Not Hispanic/Latino	Yes
E7. Race:	Asian	
	American Indian or Alaskan Native	
	Black or African American	
	White	Yes
	Native Hawaiian or Other Pacific Islander	

E8. List known medical conditions:

E9. Please list all allergies:

E10. List any other important information about the person:

E11. List all current prescription medications and medical devices being used:

E12. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used:

SECTION F - ABOUT THE PERSON FILLING OUT THIS FORM	
F1. Last Name	(b) (6)
F2. First Name	(b) (6)
F3. Number/Street	(b) (6)
F4. City and State/Province	(b) (6)
F5. ZIP or Postal Code	(b) (6)
F6. Country	US
F7. Telephone number	
F8. Email address	(b) (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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<blank>
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	(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	03/05/2019
Problem End Date	03/05/2019
Please describe the health problem or product problem.	On March 5th, I prepared a bath for my toddler and myself. I was using 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?	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	30
Select Unit of Age	year(s)
Please list any known pre-existing 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	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 e-liquid, 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	<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?	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 (either currently or in the past)?	Yes

Other Tobacco Products

Tobacco Product Type	Cigarette
Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")	Marlboro lights
Is the tobacco product currently being used?	Yes
How is the tobacco product used?	<blank>
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	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	(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?	Both (health problem that is also associated with a product problem or defect)

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

Contact Information - Sender

Organization Name	<blank>
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	(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?	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	<blank>
Birth date of the person who experienced the problem	(b) (6)
Age of the person when the problem occurred	21
Select Unit of Age	year(s)
Please list any known pre-existing 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 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)
Select all that apply to the e-liquid, 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/ 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	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>
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?	<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?	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?	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, 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	2019-04-30
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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(b) (6)
Street Address Line 2	<blank>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
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	Physician

Problem Summary

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 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?	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	[redacted]
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	(b) (6) [redacted]
Age of the person when the problem occurred	17
Select Unit of Age	year(s)

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

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 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?	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, removing a filter from a cigarette)?	Unknown

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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	05/04/2019
Problem End Date	05/04/2019
Please describe the health problem or product problem.	I experienced a minor seizure (first of my life) shortly after I started 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 or more)	None of the above
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?	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	25
Select Unit of Age	year(s)
Please list any known pre-existing 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 e-liquid, 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/ 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	Aardvark Glass
Country	United States
Phone	<blank>
Street Address Line 1	<blank>
Street Address Line 2	<blank>
City/Town	Norfolk
State	Virginia
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?	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, 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)?	Yes

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")	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

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	05-May-2019	CTU Received Date	05-May-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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	23-Apr-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)

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 was having a bbq with my family, I had 4 drinks of Jack Daniel's and coke a cola. I was smoking my vape, a lot. When we finished I cleaned up a little and I came back in the house grabbed some food to eat in the kitchen. At this point I passed out but my sister was right next to me.. she thought I was going to throw up in the sink. Because I started shaking. I hit my chin on the sink as I fell to the floor. I turned ghost white, my whole body shook. My family called 911 and I went to the hospital.. my diagnosis was hypokalemia, syncope. I believe it was the vape that caused this.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
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)	Yes

Section C – About the Product 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)	The pancake house		
Name of the company that makes (or compounds) the product	GHOST		
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 of stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?			

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
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			

	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, 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	(b) (6)
	Gender	Female
	Age (specify unit of time for age)	26 Year(s)
	Date of Birth	
	Weight	65.25 kg
	Ethnicity(Choose 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 know medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

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	

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	[redacted]
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	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):	No	


The Pancake House
Golden Maple
100ml
6mg
WARNING:
This product contains nicotine. Nicotine is an addictive chemical.
GOST
USA
The Pancake House
Golden Maple
6 mg
80 VG
20 PG
WARNING: THIS PRODUCT CONTAINS NICOTINE.
NE IS AN ADDICTIVE CHEMICAL

MedWatch 3500B Consumer/Patient Report

The FDA Safety Information and Adverse Event Reporting Program

FDA Safety Report ID #	(b)(6)	FDA Received Date	06-May-2019

SECTION A - ABOUT THE PROBLEM			
A1. What kind of problem was it?	Were hurt or had a bad side effect *(including new or worsening symptoms)*	Yes	
	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		
A2. Did any of the following happen?	Hospitalization - admitted or stayed longer	Yes	
	Required help to prevent permanent harm		
	Disability or health problem		
	Birth defect		
	Life-threatening	Yes	
	Death *(include date)*		
	Other serious/important medical incidents *(please describe)*		
A3. Date the problem occurred:	05-May-2019		

A4. Tell us what happened and how it happened:

seizure after vaping -healthy 29 year old male

A5. Relevant Tests/Laboratory Data:	
Test 1	
Test Date:	
Test Name:	
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:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 4	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

A5. Relevant Tests/Laboratory Data:	
Test 5	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 6	
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	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

A5. Additional Comments:		
adverse reaction		
Please select the cause of the problem that applies below:	Problem with a product	
	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:		
C5. Product Type:	OTC (Over-the-counter)	
	Compounded	
	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?		

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:		
C5. Product Type:	OTC (Over-the-counter)	
	Compounded	
	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?		

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:		
D6. Serial number:		
D7. UDI number:		
D8. Expiration date:		
D9. Was someone operating the medical device when the problem occurred?	Yes	
D9. If yes, who was operating it?	The person who had the problem	Yes
	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 THE PROBLEM		
E1. Person's Initials:	APS	
E2. Gender:	Female	
	Male	Yes
	Intersex	
	Transgender	
	Prefer not to disclose	
E3. Age:		
E4. Date of Birth:	(b) (6)	
E5. Weight:		
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	

E8. List known medical conditions:

None

E9. Please list all allergies:

None

E10. List any other important information about the person:

was a smoker

E11. List all current prescription medications and medical devices being used:
none

E12. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used:
protein shakes

SECTION F - ABOUT THE PERSON FILLING OUT THIS FORM	
F1. Last Name	(b) (6)
F2. First Name	[redacted]
F3. Number/Street	(b) (6)
F4. City and State/Province	(b) (6)
F5. ZIP or Postal Code	[redacted]
F6. Country	[redacted]
F7. Telephone number	(b) (6)
F8. Email address	(b) (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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	[redacted]
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	<blank>
Street Address Line 2	<blank>
City/Town	<blank>
State	(b) (6)
ZIP/Postal Code	<blank>
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	04/21/2019
Problem End Date	04/22/2019
Please describe the health problem or product problem.	I experienced two seizures less than 24 hours after heavy use of Juul 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	1

(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 pre-existing 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)	Uses prefilled cartridge, cart, cartomizers or carto.
Select all that apply to the e-liquid, 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 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	Quick Trip
Country	United States
Phone	<blank>
Street Address Line 1	<blank>
Street Address Line 2	<blank>
City/Town	<blank>
State	Georgia
ZIP/Postal Code	30080
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
Describe what substances are being mixed with the tobacco product	<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?	7

Select Unit of Measure	Month(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?	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, 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)?	Yes

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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?	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?	1
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	(b) (6)
Age of the person when the problem occurred	17
Select Unit of Age	year(s)
Please list any known pre-existing 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 e-liquid, 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	<blank>
Street Address Line 1	Aresnal St
Street Address Line 2	<blank>
City/Town	Watertown
State	New York
ZIP/Postal Code	13601
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?	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 to its use	Used a different pod.

Tobacco Product Parts

Other Products Used

Other Tobacco Products

Additional Information

Attached Files

None

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	16-May-2019	CTU Received Date	16-May-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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	29-Apr-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)

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)

Had dizziness, tingling, low blood pressure, paralysis causing hospitalization in ICU. Since then, seizure type symptoms--focal seizures

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date		
Test Result		Test Unit		
Low Test Range		High Test Range		
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
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)	Juul
Name of the company that makes (or compounds) the product	Tobacco Company
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?	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	
Frequency		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	

	Is therapy still on-going?	Yes

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Quit 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	(b) (6)
	Gender	Female
	Age (specify unit of time for age)	45 Year(s)
	Date of Birth	
	Weight	59.4 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)

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	(b) (6)
Number/Street	(b) (6) ,
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	16-May-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	

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(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?	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	(b) (6)
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	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	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 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), 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 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?	6
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, 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)?	No

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 be added on the next page.	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	(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?	Both (health problem that is also associated with a product problem or defect)

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

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<blank>
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	(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?	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 separate report for each affected person, if possible.)	User(s)
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-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 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	Electronic cigar or e-cigar
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 e-liquid, 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), 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)	Tobacco, Menthol, 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 made by Juul Labs, Incorporated, Pax, Eon Pods owned by Eon PODS LLC.
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	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
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?	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
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)?	Yes

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

FILENAME	juul-juul-pod-mango-4-pack-2_grande_aa741310-aeb3-4cbb-b5c0-b0b2529f3b03.jpg
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	(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 SRP)?	No

Contact Information - Sender

Organization Name	[redacted]
Confirm Email	(b) (6) [redacted]
First Name	(b) (6) [redacted]
Last Name	(b) (6) [redacted]
Did you report the problem to the manufacturer?	<blank>
Job Title	<blank>
Phone	(b) (6) [redacted]
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6) [redacted]
Country	United States
Street Address Line 1	(b) (6) [redacted]
Street Address Line 2	<blank>
City/Town	(b) (6) [redacted]
State	(b) (6) [redacted]
ZIP/Postal Code	(b) (6) [redacted]
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	01/15/2017
Problem End Date	<blank>
Please describe the health problem or product problem.	I had been using a vape pen in order to quit smoking. I was using a 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 overnight 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	(b) (6)
Age of the person when the problem occurred	37
Select Unit of Age	year(s)
Please list any known pre-existing 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 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)	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	<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?	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, 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")	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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	<blank>
First Name	(b) (6)
Last Name	(b) (6)
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	<blank>
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	(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 pre-existing 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/ 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>
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)?	Yes

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<blank>
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	(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	05/30/2019
Problem End Date	05/30/2019
Please describe the health problem or product problem.	Laying down when lights really started bothering me. Got up to turn 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?	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	24
Select Unit of Age	year(s)
Please list any known pre-existing 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 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	Wild side smoke shop
Country	United States
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, 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	Battery(reusable)
When was this tobacco product part purchased or acquired?	05/23/2019
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 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?	No

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	<blank>
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)?	Yes

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

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	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		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	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.

Relevant Test/Laboratory Data				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?				

Relevant Test/Laboratory Data				2 of 5
Test Name	SLEEP STUDY FOR SLEEP APNEA	Test Date		
Test Result	Possible mild-to-moderate sleep apnea	Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Relevant Test/Laboratory Data				3 of 5
Test Name	PORTABLE EKG	Test Date		
Test Result	Normal	Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Relevant Test/Laboratory Data				4 of 5
Test Name	EEG	Test Date		
Test Result	Normal	Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Relevant Test/Laboratory Data				5 of 5
Test Name	SEIZURE STUDY IN HOSPITAL	Test Date		
Test Result	Inconclusive- some abnormal brain activity in spec	Test Unit		

Low Test Range		High Test Range		
More Information Available?				

Additional Comments

These tests were done in conjunction with cardiology and neurology to determine why I was having these seizure like episodes where I would pass-out and occasionally convulse. I have done multiple EEG and EKG tests and only stated one test for each. I do not have the specific dates of these tests and I know that there are a few more that I haven't mentioned due to not having the information in front of me at the moment. I will be able to provide all medical records if needed. I ran out of space in he "What Happened" section. I will be able to provide more information and examples if requested.

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		
Type	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)	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 ☐ Biosimilar		
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		If Other	
Date the person first started taking or using the product	31-Dec-2011		

	Date the person stopped taking or using the product	01-Jan-2019	
	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

	Stop smoking tobacco

	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	(b) (6)
	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 ☐ 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)
Overweight, higher blood pressure, and Asperger's

Please list all allergies (such as to drugs, foods, pollen or others)
None known

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
smoker/vaper, occasionally drinks alcohol

List all current prescription medications and medical devices being used.
Carbamazepine

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	(b) (6)
Number/Street	(b) (6) ,
City	(b) (6)
State/Province	(b)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	03-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	

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	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		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	02-Jan-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)

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)

16 year old male had grand mal (tonic-clonic) seizure on 1/2/2019 directly after taking a hit from a Nova vape device of Mr. Salt-E Blood Orange. Same 16 year old male had a second grand mall seizure - again immediately after taking a hit from a Nova with Mr. Salt-E Blood Orange on 2/4/2019. Those are not th only times he has smoked that device/flavor, before or since.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

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	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)	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 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?	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	
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			

	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	(b)(6)
	Gender	Male
	Age (specify unit of time for age)	16 Year(s)
	Date of Birth	
	Weight	58.5 kg
	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)

Bicuspid aortic valve

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

mold, tobacco

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.

Lexapro 10mg

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

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	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	**
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	03-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	

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	(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 SRP)?	No
Describe who the problem was reported to	<blank>

Contact Information - Sender

Organization Name	<blank>
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	(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
Describe other consumer/ concerned citizen type	<blank>
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	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	(b) (6)
Age of the person when the problem occurred	36

Select Unit of Age	year(s)
Please list any known pre-existing 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.	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 product (including electronic waterpipe)	<blank>
Select all that apply to the e-liquid, 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?	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 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

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?	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?	<blank>
Select Unit of Measure	<blank>
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?	<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)?	Unknown

Tobacco Product Parts

Other Products Used

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

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 #	(b)(6)	FDA Received Date	05-Jun-2019

SECTION A - ABOUT THE PROBLEM			
A1. What kind of problem was it?	Were hurt or had a bad side effect *(including new or worsening symptoms)*	Yes	
	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		
A2. Did any of the following happen?	Hospitalization - admitted or stayed longer	Yes	
	Required help to prevent permanent harm		
	Disability or health problem		
	Birth defect		
	Life-threatening		
	Death *(include date)*		
	Other serious/important medical incidents *(please describe)*		
A3. Date the problem occurred:	04-Jun-2019		

A4. Tell us what happened and how it happened:

My daughter who is also on medications for anxietytook a few puffs of nicotine in a juul device and had a seizure. She had only prescribed medicines and doses in her system so this was the only change. The medications she is taking are Xanax XR 2mg, Adderrall 15 mg and Zoloft 150 mg.

A5. Relevant Tests/Laboratory Data:	
Test 1	
Test Date:	04-Jun-2019
Test Name:	Blood Tests and CT scan
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:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 4	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

A5. Relevant Tests/Laboratory Data:	
Test 5	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 6	
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	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

A5. Additional Comments:		
Please select the cause of the problem that applies below:	Problem with a product	
	Problem with a device	Yes

SECTION B - PRODUCT AVAILABILITY	
B1. Do you still have the product in case we need to evaluate it?	No
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:		
C5. Product Type:	OTC (Over-the-counter)	
	Compounded	
	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?		

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:		
C5. Product Type:	OTC (Over-the-counter)	
	Compounded	
	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?		

SECTION D - ABOUT THE MEDICAL DEVICE		
D1. Name of medical device:	Juul	
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	
D9. If yes, who was operating it?	The person who had the problem	Yes
	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 THE PROBLEM		
E1. Person's Initials:	[redacted]	
E2. Gender:	Female	Yes
	Male	
	Intersex	
	Transgender	
	Prefer not to disclose	
E3. Age:	17	Year(s)
E4. Date of Birth:		
E5. Weight:	98	lb
E6. Ethnicity:	Hispanic/Latino	
	Not Hispanic/Latino	Yes
E7. Race:	Asian	
	American Indian or Alaskan Native	
	Black or African American	
	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:

E11. List all current prescription medications and medical devices being used:
Xanax XR 2 Mg, Asserall 15mg, zoloft 100mg

E12. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used:

SECTION F - ABOUT THE PERSON FILLING OUT THIS FORM	
F1. Last Name	[redacted]
F2. First Name	[redacted]
F3. Number/Street	[redacted]
F4. City and State/Province	[redacted]
F5. ZIP or Postal Code	[redacted]
F6. Country	US
F7. Telephone number	[redacted]
F8. Email address	[redacted]
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

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	06-Jun-2019	CTU Received Date	07-Jun-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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

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	06-Jun-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)

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)

A couple minutes after hitting a Juul, I experienced a seizure. I don't know if the two are related, but I do know that I do not have a past history of seizures. I've been under a lot of stress, and getting very littles sleep, so that paired with the Juul may have led to my seizure.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

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)	Mint Juul pods 5% strength		
Name of the company that makes (or compounds) the product	Juul Vapor		
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?	Doesn't Apply		

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	16-Mar-2018		
Date the person stopped taking or using the product	06-Jun-2019		
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

	Recreation

	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	[redacted]
	Gender	Male
	Age (specify unit of time for age)	20 Year(s)
	Date of Birth	
	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 ☐ Asian ☑ White ☐ Black or African American

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

	None

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

	None

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

	Marijuana

List all current prescription medications and medical devices being used.

	None

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	(b) (6)
	Number/Street	(b) (6)
	City	(b) (6)
	State/Province	(b) (6)
	Country	USA
	ZIP or Postal code	(b) (6)
	Telephone number	(b) (6)
	Email address	(b) (6)
	Fax	
	Reporter Organization	
	Department	
	Reporter Speciality	

	Today's date	06-Jun-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	

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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	[redacted]
Last Name	(b) (6)
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)	(b) (6)
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

Problem Start Date	02/26/2019
Problem End Date	<blank>
Please describe the health problem or product problem.	Simple partial seizure lasting 30 seconds after using vape first thing 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	(b) (6)
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	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 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)	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/ 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?	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 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?	7
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?	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, 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)?	Yes

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
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	(b) (6)
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	(b) (6)
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	2 of my patients experienced an issue

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.	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	[redacted]
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 the affected person	none known

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 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)	<blank>
Select all that apply to the e-liquid, 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")	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?	<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?	Rarely
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 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?	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)?	Unknown

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	(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 SRP)?	No

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	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 problem	Sister

Problem Summary

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	[redacted]
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	20
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	N/A

Medications and Supplements

Please list the prescription medications, over-the-counter 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 e-liquid, 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	<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
Describe what substances are being mixed with the tobacco product	<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?	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 (either currently or in the past)?	Yes

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	(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 SRP)?	No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
Did you report the problem to the manufacturer?	<blank>
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)	Other
Describe other consumer/ concerned citizen type	Mother of a teenager consumer
Are you the person who experienced health problems associated with a tobacco product?	<blank>

Problem Summary

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?	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	14
Select Unit of Age	year(s)
Please list any known pre-existing health problems for the affected person	(b) (6) 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

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., Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user)
Select all that apply to the e-liquid, 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, Coloring Agents, Flavor(s), Glycerin, Propylene Glycol, Water
Describe other e-liquid ingredients	<blank>
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?	<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?	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?	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>
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?	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	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.	<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	(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 SRP)?	No

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 apply)	Concerned citizen
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 problem or product problem.	I experience tachycardia, exceeding 100 bpm at rest when my teen 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	(b) (6)

Age of the person when the problem occurred	36
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-the-counter 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 e-liquid, 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/ 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?	<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	<blank>
Web Address	https://glasvapor.com/collections/100ml-crystal-bottle
Email Address	<blank>

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?	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	<blank>
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?	From a Friend
Purchase Location Name	(b) (6)
Country	<blank>
Phone	<blank>
Street Address Line 1	<blank>
Street Address Line 2	<blank>
City/Town	(b) (6)
State	(b) (6)
ZIP/Postal Code	<blank>
Web Address	<blank>
Email Address	<blank>

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	<blank>
ZIP/Postal Code	<blank>
Web Address	<blank>
Email Address	<blank>

Other Products Used

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

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 Services

CDER

DQRS

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # (b) (6)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 8 Mon	☑ Female ☐ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/14/2011	09/27/2011

5. Describe Event, Problem or Product Use Error

Our child developed what appeared to be a spasm/dystonic reaction while on vacation in the UK - manifested as a recurrent, rhythmic right shoulder shrug. This faded after return to the US, but reappeared after a few weeks. I believe this is due to secondhand exposure to nicotine vapor generated by an electronic cigarette. Her father uses an e cigarette but had not, prior to her adverse reaction, used it indoors or near her. While on vacation in London, he began using the device inside our hotel room, because of questionable safety on the streets during the riots. On return to the US, he became more comfortable with its apparently safe

6. Relevant Tests/Laboratory Data, Including Dates

RECEIVED
SEP 28 2011
MEDWATCH CTU

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

2. Dose or Amount	Frequency	Route
#1		
#2		

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

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

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

6. Lot #
   #1 1
   #2

7. Expiration Date
   #1
   #2

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #
5. Operator of Device
   ☐ Health Professional
   ☐ Lay User/Patient
   ☐ Other: _____
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. Name and Address
   (b) (6)

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

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

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

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

B5. 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.

MEDWATCH

(b) (6)

For VOLUNTARY reporting by health professionals of adverse events and product problems

[redacted]

H6. FDA Comments

	Drug	Manufacturer	Dose	Unit	Route	Frequency Dosage	Interval	Unit	Is Concomitant

	Diagnosis for Use	Start Date	End Date	Duration	Unit

FDA Comments:

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wilsonj: |*********|  2011-09-28-09.02.26  |*********|
USFDAMWVOLUNTARY(b)(6)  7187_20110927.xml
Route To: AERS      :  Electronic
Route To: DQRS      :           : Paper
Route To: Misc.     :           : Paper
Send copy to Center or Tobacco Products
```

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

[redacted]

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