The following message accompanies all responses to requests made to FDA / CTP for tobacco product adverse event reports, data or analyses.

When reviewing or analyzing adverse event (AE) reports received by CTP, please note the following:

Individual AE reports about a particular product and the total number of AE reports for that product in CTP's AE database only reflect information **AS REPORTED** and do not represent any conclusion by FDA about whether the product actually caused the adverse events.

Reports to FDA may not include accurate or complete information, such as whether the product was used correctly, or if an individual also suffered from other medical conditions or took other tobacco products, medications, or drugs at the same time. When important information is missing from a report, it is difficult for FDA to fully evaluate whether the product caused the adverse event or simply coincided with it. The fact that an adverse event happened after a person has consumed a product does not necessarily mean that product caused the adverse event.

Because the database is constantly updated with new information, the number of reports for a given product and the content of individual reports may change over time.

AE reports received by CTP are submitted voluntarily. Generally only a small fraction of adverse events associated with any product is reported. Duplicate reports may be present, particularly if an event is reported through more than one source. In addition, use information for specific tobacco products is not well known. Therefore, accumulated reports cannot be used to calculate incidence (occurrence rates) or to estimate risk. Comparisons between products cannot be made from these data.

## MEDWATCH

2. Age at Time of Event, or

Date of Birth: (b) (6)

(mm/dd/yyyy)

Required Intervention to Prevent Permanent Impairment/Damage (Devices)

I have chemical irritation per my doctor throughout my mouth the tongue and throat

and now it is going down my throat

3. Sex

PRODUCT PROBLEM OR ERROR

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

Female
Male

Disability or Permanent Damage

Congenital Anomaly/Birth Defect

4. Date of this Report (mm/dd/yyyy)

03/14/2013

✓ Other Serious (Important Medical Events)

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

2. Outcomes Attributed to Adverse Event

Hospitalization - initial or prolonged

5. Describe Event, Problem or Product Use Error

6. Relevant Tests/Laboratory Data, Including Dates

burning my whole mouth.

Smoker trying to quit

I was examined by an internal medicine

doctor. He told me not to use the electronic cigarette anymore I cannot smoke regular cigarettes and most foods feel like they are

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

Returned to Manufacturer on: \_

Patient Identifier

Unspecified

Check all that apply:

1. Adverse Event

B. ADVERSE EVENT.

(Check all that apply)

Death:

Life-threatening

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

03/14/2013

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

Internet Submission - Page 1

More

More

More

(mm/dd/yyyy)

4. Weight

144

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

e errors	sequence	#		
- Page 1				
D. SUSPECT PRO	DUCT(S)			
Name, Strength, Manus		product label)		
Victory e	T.	8	Vic	tory
#1cigarettes				
#2				
2. Dose or Amount		Frequency		Route
#1 2-4 puffs		About 5	times a	
#2	***************************************			
n2				J L
3. Dates of Use (If unknow	n, give duratio	on) from/to (or		pated After Use
best estimate) 1 mon	th 1 week	k /13/2013	#1 Yes	or Dose Reduced?
#1 02/09/2013	03	, 13/4013	#1 L Yes	Apply
#2			#2 🔲 Yes	No Does
. Diagnosis or Reason for Quit smoking	or Use (Indica	tion)	8. Event Pe	eappeared After
#1			Reintrod	uction?
#2			#1 🗹 Yes	No Does
5. Lot #	7. Expiration	on Date	1	□ □ Does
		wate	#2 Yes	No Apply
#1	#1		9. NDC # or	Unique ID
#2	#2			
E. SUSPECT MEDI	CAL DEVI	CE		
. Brand Name				
. Common Device Name	,			
. Manufacturer Name, Ci	ity and State			
. Model #	Lot	#	15	Operator of Device
	250	-	"	
Catalog #	Exp	ration Date (m	m/dd/yyyy)	Health Profession
				Lay User/Patient
Serial #	Othe	er#		Other:
If Implanted Chic Pate	(mm/dd/ss	7 45	lanted Circ	Data /mm/ddf 1
i. If Implanted, Give Date	(mm/dd/yyyy)	/. п Ехр	named, GIVE	Date (mm/dd/yyyy)
. Is this a Single-use Dev	ice that was	Reprocessed a	and Reused o	n a Patient?
Yes V No				
. If Yes to Item No. 8, En	ter Name and	Address of Re	processor	
F. OTHER (CONCC				S
Product names and there	py dates (ex	clude treatment	of event)	
				More
G. REPORTER <i>(Se</i>	e confide	ntiality sect	ion on ba	ck)
. Name and Address				
(b) (6)				
b) (6)				
hone #		E-mail (b) (6	\	
. Health Professional?	3. Occupation	1.0	***************************************	Iso Reported to:
Yes V No	. occupation	•	" "	Manufacturer
				=
. If you do NOT want you			z li	User Facility
to the manufacturer, pla	ace an "X" in	uns pox:		Distributor/Importer

FORM FDA 3500 (8/05)

Yes No

C. PRODUCT AVAILABILITY

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

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

 From:
 Myers, Brooke

 To:
 Rudy, Susan

 Cc:
 Chang, Nancy

Subject: Adverse Health Event Report - Electronic Cigarettes

Date: Monday, April 01, 2013 4:43:38 PM

### Hello,

I received this call today from a woman wanting to report her adverse health event regarding electronic cigarettes (E-Cigs). Her name is and her phone number is

stated she purchased the BluCigs brand of electronic cigarettes and smoked one of them. After smoking the e-cigs, her lips swelled four times the size of her lip and she had trouble breathing. She then went to the emergency room and on top of the previous symptoms, she had a rash in her mouth, her face was swollen, and her throat was itchy and numb. The doctors ran test and found an antihistamine in her blood stream that came from e-cigs. She had to get steroids and an IV. She contacted the company, but couldn't get in contact with anyone because they didn't answer the call. She contacted them to inform the company of what happened, to ask for a full refund, and ask that they pay her medical bills.

The incident took place on

Thank you,

### Brooke Myers

Program Analyst FDA/CTP/OM/M&L 9200 Corporate Blvd. Rockville, MD 20850 Phone: 301.796.0334 Fax: 240-276-1705

Success is not the key to happiness. Happiness is the key to success. If you love what you are doing, you will be successful." ------Albert Schweitzer

# MEDWATCH

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

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

	product us	se errors	Triage unit sequence #				
The FDA Safety Information and Inter Adverse Event Reporting Program	rnet Submission	- Page 1					
A. PATIENT INFORMATION		D. SUSPECT PROD	HCT(S)				
1. Patient Identifier Female from (b) (6)  2. Age at Time of Event, or Date of Right (b) (6)  3. Sex  Female	4. Weight 180 lb	1. Name, Strength, Manufa E ciggs #1		duct label)	E ci	iggs	
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERF	BOB	#2					
Check all that apply:		2. Dose or Amount		requency		Route	
Adverse Event Product Problem (e.g., defects/malfunction Product Use Error Problem with Different Manufacturer of	,	#1 The highest do	Joaye, II	Several da	times a	Inhal	
2. Outcomes Attributed to Adverse Event		#2				<u> </u>	
(Check all that apply)		<ol> <li>Dates of Use(If unknown best estimate)</li> </ol>	n, give duration) i	from/to (or	5. Event Aba	ated After l or Dose Re	
Death: Disability or Permaner  (mm/dd/yyyy)  Congenital Anomaly/E		#1 01/01/2011	06/0	1/2011	#1 Yes		Doesn't Apply
Hospitalization - initial or prolonged Other Serious (Import	ant Medical Events)	#2			#2 🗌 Yes	☐ No	Doesn't Apply
Required Intervention to Prevent Permanent Impairment/Damage (I	Devices)	4. Diagnosis or Reason for I was a curren		)	8. Event Rea	ppeared #	
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (m	m/dd/yyyy)	#1			Reintrodu	_	☐ Doesn't
01/01/2009 04/22/2013		#2			#1 Yes	<b>∠</b> No	Apply
5. Describe Event, Problem or Product Use Error		6. Lot #	7. Expiration [	Date	#2 Yes	☐ No	Doesn't Apply
I visited the ER several times due		#1	#1		9. NDC # or	Unique ID	ОРРІУ
shortness of breath, heart palpatat		#2	#2			•	
chest pain. Upon arrival to the ER occassions my blood pressure was el		E. SUSPECT MEDIC	CAL DEVICE				
Although all cardiac testing came b	ack	1. Brand Name					
negative I did come back positive f		E ciggs 2. Common Device Name					
marijuanna which was impossible. I ciggs after that.	quit E	E ciggs					
orage areer enac.		3. Manufacturer Name, Cit I purchased in (k					
		2 paramata 2n					
		4. Model #	Lot #		5. (	Operator o	1 Device
		Catalog #	Expirati	on Date (mn		Health P	Professional
			2.4	on oute (iiiii		Lay Use	r/Patient
		Serial #	Other #		L	_ Other:	
		6. If Implanted, Give Date (	(mm/dd/ww)	7 If Expl	anted, Give D	ate (mm/di	d(anay)
				/. W Cxpr	unica, arre o	are (innece	** } } } )
		8. Is this a Single-use Devi	ce that was Rep	processed a	nd Reused on	a Patient	?
		Yes ✓ No 9. If Yes to Item No. 8, Ente	ar Name and Ad	Idraes of Bo	processor		
	More	3. Il res to hem No. 6, Eme	er Name and Ad	uress or ne	processor		
Relevant Tests/Laboratory Data, Including Dates							
EKG norlam, cardiac enzymes normal, was positive with marijuana.	drug tes						
		F. OTHER (CONCO) Product names and therap					
		E ciggs	y dates (excide	e treatment (	n event)		
	More						
Other Relevant History, Including Preexisting Medical Conditions (erace, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)	Language and the same of the s	G. REPORTER (See	confidentia	ality sacti	on on hac	<i>k</i> )	More
I have been a smaler for about 20 ye	1 1	Name and Address	- connuentia	mly secu	on on bac	7	
no symptoms like this prior to E cig		(b) (6)					
since I quit E ciggs.						.) (0)	
		(b) (6)	(b	<del></del>	(b	) (6)	
	More	Phone # (b) (6)		E-mail (b) (6)			
C. PRODUCT AVAILABILITY		2. Health Professional? 3.	Occupation			so Reporte	d to:
roduct Available for Evaluation? (Do not send product to FDA)		✓ Yes 🗌 No 1	Wurse			Manufactu	
Yes No Returned to Manufacturer on:	n/dd/vvvv)	5. If you do NOT want your to the manufacturer, place				User Facil	· I

U.S. Department of Health and Human Services

For VOLUNTARY reporting of adverse events, product problems and

product use errors
Submission - Page 1 /2

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

	Form Appro	ved: OMB		-0291, Ex 1B statem	
		FDA U	ISE ONL	Υ	
Triage seque	e unit ence #				
CT(S	5)				

The FDA Safety Information and		•	use cirois	sequenc
Adverse Event Reporting Program	Inter	net Submissio	on - Page 1/2	
A. PATIENT INFORMATION			D. SUSPECT PE	PODUCT(S)
Patient Identifier 2. Age at Time of Event	t, or 3. Sex	4. Weight	Name, Strength, M	
(b) (6)  Date of Birth:	Female	196 <sub>ib</sub>	Firebrand	andiacturer (no)
(b) (d)	Male	orkg	#1 blu cigs	
B. ADVERSE EVENT, PRODUCT	PROBLEM OR ERE		#2	
Check all that apply:	THOUSELIN OTTEN	1011	<ol><li>Dose or Amoun</li></ol>	t
_	em (e.g., defects/malfunction	one)	#1 as desired	
Product Use Error Problem with I				
2. Outcomes Attributed to Adverse Event	Sincrett Walturacturer Of	Same wedicine	#2	
(Check all that apply)			3. Dates of Use(If unit	known, give durat
Death:	Disability or Permaner	nt Damage	hest estimate)	nonth
(mm/dd/yyyy)  Life-threatening	Congenital Anomaly/E	Rirth Defect	#1 02/28/2013	03
Hospitalization - initial or prolonged	Other Serious (Import		#2	
Required Intervention to Prevent Perman	_		4. Diagnosis or Reas	on for Use (Indic
			smoker #1	
	4. Date of this Report (m.	m/dd/yyyy)		
02/28/2013	04/25/2013		#2	
5. Describe Event, Problem or Product Use E			6. Lot #	7. Expirati
This is in response to			#1 don't hav r	etu:
a report on my experie			#2	#2
cigarettes. I've used with different ingredie			E. SUSPECT M	DICAL DEV
nicotine. Very bad expe			1. Brand Name	
brand I used, which we			Firebrand	
e-cigs. I purchased the			2. Common Device N	
recommendation. My dial			electronic ci 3. Manufacturer Name	
pretty good control, e			1023 S. Santa	Fe Ave. Lo
I shouldn't my sugar ne				
went back to my norm an			4. Model #	Lot
I suddenly shot up, of			on bottle liqu	
a couple of weeks to re caused by the Firebrand			Tobacco Gold,	01/0
contain the polypropand			Serial #	Oth
They	g		none unless on	- 1
_		i	6. If Implanted, Give I	Date (mm/dd/yyyy
			8. Is this a Single-use	
		l	Yes √ No 9. If Yes to Item No. 8	
		More	9. II TES IO REIII NO. 6	, Enter Name and
6. Relevant Tests/Laboratory Data, Including	Dates			
			·	
·				
			F. OTHER (CON	COMITANT
			Product names and t	
		More		
<ol> <li>Other Relevant History, Including Preexisti race, pregnancy, smoking and alcohol use, liv</li> </ol>	ng Medical Conditions (e er/kidney problems, etc.)	.g., allergies,	G. REPORTER	(See confide
no allergies, Type II d		I	Name and Address	See connue
neuropathy, No alcohol			(b) (6)	
Bipolar		1		
			(b) (6)	
		Language	Phone #	
0.000		More	(b) (6)	010.5
C. PRODUCT AVAILABILITY			2. Health Professional	
Product Available for Evaluation? (Do not sen			Yes V No	Consumer
Yes No Returned to Man	nufacturer on:03/12/	2013	5. If you do NOT want	your identity dis

(mm/dd/yyyy)

D. SUSPECT PROD				
1. Name, Strength, Manuf Firebrand #1	acturer (from	product label) mg, 18 mg	Ludov	ico, Inc.
blu cigs				
2. Dose or Amount		Frequency		Route
#1 as desired		every da	Y	ро
#2				
3. Dates of Use(If unknown	n, give duratio	nn) from/to (or	5. Event Abate	d After Use
best estimate) 1 mont		/18/2013		Dose Reduced?
#1 02/28/2013	03/	18/2013	#1 W/_ Tes [	Apply Apply
#2 4. Diagnosis or Reason fo		tion)	#2 Yes	☐ No ☐ Doesn't Apply
smoker #1	ose (morea	aon	8. Event Reap	
#2			#1 🗹 Yes [	No Doesn't
6. Lot#	7. Expiratio	n Date	#2 Yes	No Doesn't
#1 don't hav retu	#1		9. NDC # or Ur	Apply Apply
#2	#2		don't ha	
E. SUSPECT MEDIC	CAL DEVI	CE		
Brand Name     Firebrand				
2. Common Device Name				
electronic cigar  3. Manufacturer Name, Cit				
1023 S. Santa Fe	-	s Angeles,	CA   9002	1
4. Model #	Lot #	ļ	5. Op	perator of Device
on bottle liquite		ottle sent		Health Professional
Catalog # Tobacco Gold,	Expiration Date (mm/dd/yyyy)  01/01/2000  Lay User/Patien			
Serial #	Othe			Other:
none unless on				
6. If Implanted, Give Date	(mm/dd/yyyy)	7. If Expl	anted, Give Date	e (mm/dd/yyyy)
8. Is this a Single-use Dev	ice that was	Reprocessed a	nd Reused on a	Patient?
9. If Yes to Item No. 8, Ent	er Name and	Address of Re	processor	
F. OTHER (CONCO	MITANT)	MEDICAL P	RODUCTS	
Product names and therap	py dates (exc	lude treatment o	of event)	
				1
				ľ
				More
G. REPORTER (See	e confider	itiality secti	on on back)	
1. Name and Address (b) (6)				1
(b) (6)				
Phone #		E-mail (b) (6)		
(D) (D) 2. Health Professional? 3	Occupation		4. Also	Reported to:
		Non-Healt	.   -	lanufacturer
5. If you do NOT want your to the manufacturer, pla			_   =	ser Facility
sion that medical person				



### B5. Describe event or problem continued

willingly gave me a refund but they said they had never heard of it before. If you google for it, they MUST know. Then I bought the Blu e-cigs. have had no problems. They say they don't use that chemical, rather they use a vegetable based product. I am smoking the high nicotine now and plan to phase smoking out.

Mail to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787 1-800-FDA-0178



MED WATCH

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

product use errors
Internet Submission - Page 1

orm Approved: OMB	No. 0910-0291, Expires: 10/31/08
3,55	See OMB statement on reverse.

- Page 1				
D. SUSPECT PE	RODUCT(S)	Too and sen		
1. Name, Strength, M Metro E cig #1		product label) g	Ni	cotek
#2  2. Dose or Amount		Frequency		Route
#1 a few puff:		aprox 5	x- day	ро
#2				
Dates of Use (If unit best estimate)	10000	n) from/to (or		Abated After Use ed or Dose Reduced?
#1 01/01/2013	1/2 months 03/	12/2013	#1 🗸 Y	es No Doo
#2			#2 Y	es No Doe
4. Diagnosis or Reas- lessen dep	on for Use (Indicati endance on n		Reintro	Reappeared After oduction?
#2			#1 L Y	es No Map
6. Lot #	7. Expiration	n Date	#2 🗌 Y	es No Z Do
#1	#1		9. NDC #	or Unique ID
#2	#2			
E. SUSPECT M	EDICAL DEVI	CE	NAME OF	所如非洲的
	lama.			
2. Common Device N	iante			
4. Model # Catalog #	Lot #	ration Date (n	nm/dd/vvvv)	5. Operator of Device.  Health Professi
Serial #	Othe	SAIN TO COMPANISHING		Lay User/Patier Other:
6. If Implanted, Give	Date (mm/dd/yyyy)	7. If Ex	planted, Giv	e Date (mm/dd/yyyy)
8. Is this a Single-use		Reprocessed	and Reuse	d on a Patient?
9. If Yes to Item No. 8		Address of R	leprocessor	
F. OTHER (CO	NCOMITANT)	MEDICAL	PRODUC	TS
Product names and				
-				
0 05000555	/C	-Ai-fit		Mon
	(See confider	mainty sec	non on L	Dack)
	7.0			
1. Name and Addres (b) (6)				
1. Name and Addres		E-mail (b) (		

User Facility

Distributor/Importer

The FDA Safety Information and Internet Submissio **Adverse Event Reporting Program** A. PATIENT INFORMATION 2. Age at Time of Event, or 3. Sex 1. Patient Identifier Date of Birth: √ Female (b) (6) Male B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine **Outcomes Attributed to Adverse Event** (Check all that apply) Disability or Permanent Damage Death: (mm/dd/yyyy) Congenital Anomaly/Birth Defect ✓ Other Serious (Important Medical Events) Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices) Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 04/29/2013 03/12/2013 5. Describe Event, Problem or Product Use Error I was a cig smoker for 40 + years and have COPD. I quit smoking and was using the lowest Nicotene replacement Lozengers -2mg.-When I saw that the e cig was less nicotene than the Lozengers I started puffing them. Being a former smoker I could not help but inhale, after about a month of using the e cig I found my breathing -which had improved- was getting bad again and I was starting to cough with mucus again in the mornings. I am now back on the lozengers the cough/mucus has gone away. Would love to quit nicotine all together but "I HOPE" the lozenger will not hurt my lungs as much as inhaling. More 6. Relevant Tests/Laboratory Data, Including Dates None, just personal experience. More Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc., See # 5 above.

✓ Yes No

C. PRODUCT AVAILABILITY

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

Returned to Manufacturer on:

5. If you do NOT want your identity disclosed

to the manufacturer, place an "X" in this box:

More

(mm/dd/yyyy)

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See PRA statement on reverse.

a

For VOLUNTARY reporting of	
dverse events, product problems and	

adverse events, product use	-	Triage unit	OSE ONE!
DA Safety Information and		sequence #	
Auverse Event Reporting Frogram		Fraguenay	Route
A. PATIENT INFORMATION  1. Patient Identifier   2. Age at Time of Event or   3. Sex   4. Weight	2. Dose or Amount	Frequency	Noute
Date of Birth:	Small Boffics		
59 (b) (c)	#2 Scented OTL	S 2-Scents	
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	3. Dates of Use (If unknown	100	5. Event Abated After Use
Check all that apply:	(or best estimate)		Stopped or Dose Reduced? #1 Yes No Doesn't
1. ☐ Adverse Event ☑ Product Problem (e.g., defects/malfunctions) ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine	#7-1005 -2day's-	65/11/5,	#2 Yes No Doesn't
2. Outcomes Attributed to Adverse Event	4. Diagnosis or Reason for	Use (Indication)	8. Event Reappeared After
(Check all that apply)  Death: Disability or Permanent Damage	J-11-5013.47-	12-2013	Reintroduction?
(mm/dd/yyyy)  Life-threatening  Congenital Anomaly/Birth Defect	She Smoked E-	Cian. 85116	Apply
☐ Hospitalization - initial or prolonged 📈 Other Serious (Important Medical Events)	6. Lot # 1	7. Expiration Date	#2 Yes No Doesn't Apply
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	#1	#1443-2013	9. NDC # or Unique ID
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)	E. SUSPECT MEDIC	#2	
5. Describe Event, Problem or Product Use Error	1. Brand Name	AL DEVICE	
			`
Electronic Ciggaretts	2. Common Device Name		2b. Procode
Sented Oil's	e.		
2611 COV ()122	3. Manufacturer Name, City	and State	
dat wid bestrang			
DIY a rough act MP	4. Model #	Lot#	↑ 5. Operator of Device
To the texton well			Health Professional
T Carrida District	Catalog #	Expiration Date (mn	n/dd/yyyy)
& severe congestion			Other:
6. Relevant Tests/Laboratory Data, Including Dates	Serial #	Unique Identifier (U	
t to the contract of the contr			
	6. If Implanted, Give Date (	mm/ed/yyyy) 7. If Exp	planted, Give Date (mm/dd/yyyy)
•	8 is this a Single-use Devi	ce that was Reprocesse	ed and Reused on a Patient?
	Yes No		
	9. If Yes to Item No. 8, Enter	Name and Address of Re	processor
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)	• • • •		. <b>*</b> * • • • • • • • • • • • • • • • • • •
		MITANT) MEDICAL	
	Product names and therap	y dates (exclude treatme MOUNULACA	ent of event)
	01000	<b>X X</b> · · · · · · · · · · · · · · · · · · ·	TUVELE
	T MOINT L	2 KUOM	
	G. REPORTER (See		on on back)
C. PRODUCT AVAILABILITY	1. Name and Address (Name (b) (6)	b) (6)	
Product Available for Evaluation? (Do not send product to FDA)	Address:		
Yes No Returned to Manufacturer on:	<sub>City</sub> (b) (6)	· .	te: ZIP: (b) (6)
D. SUSPECT PRODUCT(S)		Sta E-mail	ie: ZIP:
1. Name, Strength, Manufacturer (from product label) #1 Name: ELECTION'S C 1990/eth	Phone # (b) (6)		
1. Name, Strength, Manufacturer (from product label) #1 Name: ELECTRON'S CI999XETT Strength: Manufacturer: DiFFerent OIL Scent'S	2. Health Professional? 3.	Occupation	4. Also Reported to:
Manufacturer: #2 Name:	Yes X No		Manufacturer
Strength:	5. If you do NOT want your i		User Facility Distributor/Importer
Manufacturer:	to the manufacturer, place	ean vilinis box: 📐	

PLEASE TYPE OR USE BLACK INK

DIFFERENT OIL Strength: Manufacturer: #2 Name: Strength: Manufacturer: FORM FDA 3500 (2/13)

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

U.S. Department of Health and Human Services

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

Form Approved:	OMB No. 0910-029	1, Expires: 10/31/08
	See OMB st	atement on reverse.

FDA USE ONLY

IVIED			au		luct use e	rrors		age unit quence #	+				
•	Information and Reporting Progran	n	Inter	net Submi	ssion - 1	Page 1							
A. PATIENT IN					D.	SUSPECT PRO	ODUCT	(S)					
	2. Age at Time of Eve Date of Birth: (b) (6)	🖳	Female	4. Weight 163		lame, Strength, Mar liquid	_		roduct label)		White	Rhi	no
In confidence	37 Years	-	Male		kg #2	2							
Check all that apply:	EVENT, PRODUCT	PROBLEM	OR ERR	OR	2.	Dose or Amount			Frequency			Route	
1. Adverse Ever	nt  Product Prof	olem (e.g., defects	/malfunctiv	nne)	#	1				•			
Product Use	-	Different Manufa			,     #:	,						_	===
2. Outcomes Attribu	ited to Adverse Event			<del></del>	<u> </u>	· L			L			<u> </u>	
(Check all that app	oly)					Dates of Use(If unkn best estimate)	own, give	duration	) from/to (or			ed After	r Use Reduced?
Death:	(mm/dd/yyyy)	_ U Disability or	Permaner	nt Damage	#	1				I —	Yes	_	Doesn'
✓ Life-threatenin	-	Congenital /	•		-								Apply  Doesn'
	n - initial or prolonged			ant Medical Eve	''''''	Ziagnosis or Reason	n for Use	(Indication	on)		Yes		L Apply
	rvention to Prevent Perma	1			#-						nt Reap troduc	peared tion?	After
3. Date of Event (mn 05/29/20	,	4. Date of this F	Report (mi	m/dd/yyyy)	-	····				#1 🗌	Yes	☐ No	Doesn' Apply
	Problem or Product Use		,		——	ot #	7. Ex	cpiration	Date		I		Doesn'
İ	i was chargin		ita P	hino	#1	na					Yes		☐ Apply
	te, when we h				-		_   #1			9. NDC	# or U	nique II	)
	ad exploded.				#2		#2	DEVIC	_	II d			
	our home ar					SUSPECT ME Brand Name	DICAL	DEVIC	· E				
_	room. It sta If my daughte				,	iquid							
	ed it would h				1   12.1	Common Device Na hite Rhino	me						
						fanufacturer Name,	City and	State					
					l w	nite Rhino							
					4. 1	Model #		Lot #			5. <b>Q</b>	perator	of Device
					na			na			╛┌	Health	Professional
						Catalog #		Expire	ation Date (m	m/dd/yyy)	" Z	Lay Us	ser/Patient
					na	Serial #		Other	#		$\dashv$	Other:	
					na								
		CTU			6.1	Implanted, Give Da	ate (mm/d	d/yyyy)	7. If Exp	lanted, G	live Da	te (mm/	'dd/yyyy)
					8.1	s this a Single-use I	Device the	at was R	eprocessed :	and Reus	ed on	a Patier	nt?
		MAY 3 0 2	2013			Yes 🕢 No							
			2013	Моз	9. 1	Yes to Item No. 8,	Enter Nar	me and /	Address of Re	eprocess	or		
6. Relevant Tests/La	aboratory Data, Includin	ng Dates		Lands									
	boratory Data, moradin	ig Daile											
					F.	OTHER (CON	COMITA	ANT) N	IEDICAL F	RODU	CTS		
					Pro	oduct names and the	erapy dat	es (excl	ude treatment	of event)			
					_								
				Mox	:0								More
	istory, including Preexis moking and aicohol use,			e.g., allergies,	G.	REPORTER (	See coi	nfiden	tiality sec	ion on	back	)	
					1. 1	lame and Address						·	
					(b	) (6)							
					Pho	ne #			E-mail				
				Moz	е	(b) (6)			(b) (6	)			
C. PRODUCT A					2. 1	lealth Professional?	1	upation	w		_	o Repor	
Product Available fo	or Evaluation? (Do not se	end product to FD/	4)			_ Yes 🗹 No			Non-Heal	ćΤ	=	Manufad User Fa	
Yes 🗌 N	o Returned to M	lanufacturer on:	(mn	n/dd/yyyy)		you do NOT want y the manufacturer,				_			tor/Importer
			Linn				-				1		

PLEASE TYPE OR USE BLACK INK

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

Form Approved: OMB	No.	0910-0291,	Expires:	12/31/20	31
		See OMB st	atement	on rever	S€

The FDA Safety Information and	Page	of			
Adverse Event Reporting Program		D. SUSPECT PRODU	CT(S)		
A. PATIENT INFORMATION  1. Patient Identifier 2. Age at Time of Event, or 3. Sex	4. Weight	Name, Strength, Manufact		ct label)	
(b) (6) Date of Birth: Female	145 b	#1 Super V	200W	E.Cia	·
In confidence (b) (6)	or kg	#2		<u> </u>	
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROF	₹	2. Dose or Amount	Free	quency	Route
Check all that apply:	.,	#1			
Adverse Event     Product Problem (e.g., defects/malfunctions     Product Use Error Problem with Different Manufacturer of Sai		#2			
Outcomes Attributed to Adverse Event     (Check all that apply)		3. Dates of Use (If unknown,	give duration) fro		Abated After Use
Death: Disability or Permanent D	Damage	best estimate)	0 10		ed or Dose Reduced?
(mm/dd/yyyy)  ☐ Life-threatening ☐ Congenital Anomaly/Birth	n Defect	#14-21-13 \$ 5	273	—   <del></del> -	Apply
Hospitalization - initial or prolonged Other Serious (Important	Medical Events)	#2 4. Diagnosis or Reason for U	Ise (Indication)	#2 Y	es No Apply
Required Intervention to Prevent Permanent Impairment/Damage (Devi	ices)	#1	ose (massumony		Reappeared After oduction?
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)	dd/yyyy)		The second of	#1 🔲 Y	es No Doesn't
5. Describe Event, Problem or Product Use Error	013	#2 6. Lot #	7. Expiration Dat	te #2 D	es No Doesn't
5 Describe Event, Problem of Product Use Error  Super Valoue E Cia explo	xled		#1	#2	or Unique ID
while charains raiseins	1st and	#2	#2		
while charging Causing and 3rd degree burns on m	w arm	E. SUSPECT MEDICA 1. Brand Name	AL DEVICE		
Elbow, hip, butt & Ankle. Dar	nage to	2. Common Device Name		©T.	Li .
my couch, Area eng & floor!	took	3. Manufacturer Name, City	and State	MAY 2 9	
many Pictures & have Perman		4. Model #	Lot#	"AI & Y	5. Operator of Device
scarring!					Health Professional
3234 7 11 23	1	Catalog #	. Expiration	n Date (mm/dd/yyyy)	Lay User/Patient
·		Serial #	Other #		Other:
		6. If Implanted, Give Date (n	nm/dd/yyyy)	7. If Explanted, Given	ve Date (mm/dd/yyyy)
		8, Is this a Single-use Device Yes	e that was Repr	ocessed and Reuse	d on a Patient?
		9. If Yes to Item No. 8, Enter	r Name and Add	ress of Reprocessor	
6. Relevant Tests/Laboratory Data, Including Dates					
moctors appt on 5-15-13				٠,	,
Doctors APAT on 5-15-13 Antibotics & Burn Cream					
		F. OTHER (CONCOL			TS
•		Product names and therap	y dates (exclude	treatment of event)	1
- Otto D. Lord History Including Proceeding Medical Conditions (c. C.	allargies				
<ol> <li>Other Relevant History, Including Preexisting Medical Conditions (e.g. race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)</li> </ol>	,, anergies,	G. REPORTER (See		ity section on b	pack)
		1. Name and Address (b)	(6)		
		(6)			
		Phone #(b) (6)	- ^ ^	E-mail	
C. PRODUCT AVAILABILITY		2. Health Professional? 3.	Occupation		4. Also Reported to:
Product Available for Evaluation? (Do not send product to FDA)		☐ Yes <b>∑</b> lo	House .	ife	Manufacturer
Returned to Manufacturer on:		5. If you do NOT want your			User Facility
(mm/	/dd/yyyy)	. to the manufacturer, place	ce an "X" in this	DOX:	Distributor/Importer

Triage unit

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

For VOLUNTAR Contring of
adverse events, product problems and
product use errors /
Tatamati Submission - Dage 1 / A

CTD	Fo	orm Approved: C	MB No. 0910-0 See OME	0291, Expires: 10/31/08 3 statement on reverse.
uct problems and	Trions uni		A USE ONLY	
e errors /	Triage uni sequence			
- Page 1/3				
D. SUSPECT PROD				
<ol> <li>Name, Strength, Manufa Nicomate premiu</li></ol>	m.	product label)	Nico	mate
#2				
2. Dose or Amount		Frequency		Route
#1 2 or 3 tips da	ily	most of	day	Inhal
#2				
Dates of Use(If unknown best estimate)	, give duratio	on) from/to (or		ited After Use or Dose Reduced?
#1 05/26/2013	05,	/28/2013	#1  Yes	No Doesn't Apply
#2		er-al	#2 Yes	□ No □ Doesn't Apply
4. Diagnosis or Reason for Stop smoking a #1		uon)	8. Event Rea Reintrodu	ppeared After ction?
#2			#1 Yes	☐ No ☑ Doesn't Apply
6. Lot#	7. Expiration	on Date	#2 🗌 Yes	□ No □ Doesn't Apply
#1 n/a	#1		9. NDC # or	Unique ID
#2	#2		none	
E. SUSPECT MEDIC  1. Brand Name NICOmate premium  2. Common Device Name			rettes	
NICOmate  3 Manufacturer Name Cit	v and State			
3. Manufacturer Name, Cit NICOmate.com, 74	-	Hill Far	m Dr. Man	chester, MO
3. Manufacturer Name, Cit	-			Chester, MO
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model #	6 Spring Lot	#	5.	
3. Manufacturer Name, Cit NICOmate.com, 74 63021	6 Spring Lot	#	5. m/dd/yyyy)	Operator of Device  Health Professional Lay User/Patient
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model #	6 Spring Lot	# Identification Date (m	5. m/dd/yyyy)	Operator of Device  Health Professional
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model # Catalog #	Lot none Exp	# Piration Date (m	5. m/dd/yyyy)	Operator of Device  Health Professional Lay User/Patient Other:
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model # Catalog # Serial #	Lot none Exp Oth	# or # or # 7. If Exp	m/dd/yyyy)	Operator of Device  Health Professional Lay User/Patient  Other: Myself/patie  Heate (mm/dd/yyyy)
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model # Catalog # Serial # 6. If Implanted, Give Date 8. is this a Single-use Dev	Lot none Exp Othe	# or	m/dd/yyyy)  Solanted, Give D  and Reused or	Operator of Device  Health Professional Lay User/Patient  Other: Myself/patie  Heate (mm/dd/yyyy)
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model # Catalog # Serial # 6. If Implanted, Give Date B. is this a Single-use Dev Yes V No	Lot none Exp Othe	# or	m/dd/yyyy)  Solanted, Give D  and Reused or	Operator of Device  Health Professional Lay User/Patient  Other: Myself/patie  Heate (mm/dd/yyyy)
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model # Catalog # Serial # 6. If Implanted, Give Date B. is this a Single-use Dev Yes V No	Lot none Exp Othe	# or	m/dd/yyyy)  Solanted, Give D  and Reused or	Operator of Device  Health Professional Lay User/Patient  Other: Myself/patie  Heate (mm/dd/yyyy)
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model # Catalog # Serial # 6. If Implanted, Give Date B. is this a Single-use Dev Yes V No	Lot none Exp Othe	# or	m/dd/yyyy)  Solanted, Give D  and Reused or	Operator of Device  Health Professional Lay User/Patient  Other: Myself/patie  Heate (mm/dd/yyyy)
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model # Catalog # Serial # 6. If Implanted, Give Date # 8. Is this a Single-use Dev Yes No 9. If Yes to Item No. 8, Ent	Lot none Exp Othe	# er # 7. If Exp Reprocessed d Address of R	m/dd/yyyy)  Solianted, Give D  and Reused or  eprocessor	Operator of Device  Health Professional Lay User/Patient Other: Myself/patie Pate (mm/dd/yyyy) n a Patient?
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model #  Catalog #  Serial # 6. If Implanted, Give Date Yes V No 9. If Yes to Item No. 8, Ent	Lot none Exp Othe (mm/dd/yyyy) ice that was	# er # 7. If Exp Reprocessed d Address of R	m/dd/yyyy)  Solianted, Give D  and Reused or  eprocessor	Operator of Device  Health Professional Lay User/Patient Other: Myself/patie Pate (mm/dd/yyyy) n a Patient?
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model # Catalog # Serial # 6. If Implanted, Give Date # 8. Is this a Single-use Dev Yes No 9. If Yes to Item No. 8, Ent	Lot none Exp Othe (mm/dd/yyyy) ice that was er Name and	# or	olanted, Give D and Reused or eprocessor	Operator of Device  Health Professional Lay User/Patient Other: Myself/patie Pate (mm/dd/yyyy) n a Patient?
3. Manufacturer Name, Cit NICOmate.com, 74 63021 4. Model # Catalog # Serial # 6. If Implanted, Give Date Yes V No 9. If Yes to Item No. 8, Ent	Lot none Exp Othe (mm/dd/yyyy) ice that was er Name and	# or	olanted, Give D and Reused or eprocessor	Operator of Device  Health Professional Lay User/Patient Other: Myself/patie Pate (mm/dd/yyyy) n a Patient?

A. PATIENT INFORMATION			
Patient Identifier 2. Age at Time of Even	t, or	3. <b>Sex</b>	4. Weight
(b) (6) Date of Birth:	l	✓ Female	310 lb
In confidence 38 Years		Male	orkg
B. ADVERSE EVENT, PRODUCT	PROB	LEM OR ERRO	OR
Check all that apply:			
1. Adverse Event Product Proble	em (e.g.	, defects/malfunction	ns)
Product Use Error Problem with	Different	t Manufacturer of S	ame Medicine
2. Outcomes Attributed to Adverse Event			
(Check all that apply)			
Death: 01/01/2013 (mm/dd/yyyy)	🔽 Dis	ability or Permanent	Damage
✓ Life-threatening	✓ Cor	ngenital Anomaly/Bir	th Defect
✓ Hospitalization - initial or prolonged	<b>√</b> Oth	ner Serious (Importar	nt Medical Events)
Required Intervention to Prevent Perman	nent Imp	airment/Damage (De	evices)
3. Date of Event (mm/dd/yyyy)		of this Report (mm	
05/28/2013	4. Date	06/12/2013	/uu/yyyy/
5. Describe Event, Problem or Product Use I	L		
****No death, no hospi			
disability, no birth d	etec	t. This ic	rm is
making me check EVERYT last 17 minutes, "plea	HING	above, it	nas for
it says, frustrating!	5 <del>6</del> C	Nicomate	nemue
electronic cigarette,	Nico		They're
all dangerous to lungs			
smoking and thought I	woul	d try the	
electronic cigarette N	icom	ate. I use	d the
regular tobacco tips.			
used it for 3 days, an			
sleep, woke up dreamin	g ab	out a norr	the small
smell in my lungs, aft lasted for 8 hours and	er r	woke up	Tt was
in my lungs and was al			
In any range and was ar			
1			
			More
6. Relevant Tests/Laboratory Data, Including	o Dates		
,	,		
n/a			
			More
7. Other Relevant History, Including Preexis	ting Me	dical Conditions (e.	g., allergies,
race, pregnancy, smoking and alcohol use, l			_
I smoke 3 packs cigare			
now. I have asthma, a			
2 inhalers, 2 daily al	rerg	y meas., 8	cpap.
My lungs are			_
			More
C. PRODUCT AVAILABILITY			
Product Available for Evaluation? (Do not se	and produ	uct to FDA)	
✓ Yes □ No □ Returned to M	anufactu	rer on:	
I II 169   INO   Heturned to Mi	untulation		

(mm/dd/yyyy)



#### B5. Describe event or problem continued

Plastic/metal/chemical. Imagine the whole mixture very powerful, and it's in your lungs. Nothing would get rid of it, it's all I could inhale or exhale. I was scared and ready to have the ER check it out, but what could they do, as it did pass after 8 hours and I have not or will not touch it again. People need to know how terrible these are on your lungs! Plastic/metal/chemical in lungs was awful!

Mail to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787

1-800-FDA-0178



### B7. Other relevant history, including preexisting medical conditions continued

sensitive to everything. Was told couldn't work in plastic factories, fibers get stuck in my lungs even with face mask on. Passed out at (b)(6) lead smelter first 2 days in a row while wearing helmet, boots, and breathing apparatus, full suit. Nurse there said I could not work around the lead. I smelled a gas leak in the inside wall of my gas station to one of the lines outside that not even the techs could find. I have serious sensitive lungs. History of a few pneumonia, bronchitis with asthma episodes. No pregnancies. White female. Alcohol, age 19 - 25. Only fatty liver, no kidney problems. Hibernoma in left foot removed (b)(6)

Mail to: MEDWATCH
5600 Fishers Lane

or FAX to:

Rockville, MD 20852-9787

1-800-FDA-0178

For VOLUNTARY reporting of adverse events, product problems and

Form Approved:	OMB	No.	0910-0	291,	Expire	S:	10/31/	08
		Se	e OMB	stat	ement	on	revers	e.

Distributor/Importer

MEDI	WATCH	■ adv		ARY reporting of oduct problems and	F	DA USE ONLY
		au		use errors	Triage unit sequence #	
The FDA Safety	Information and Reporting Program	Inter	net Submissio	n - Page 1		
A. PATIENT INF				D. SUSPECT PRO	DUCT(S)	
	2. Age at Time of Event Date of Birth: (b) (6)	t, or 3. Sex Female	4. Weight 270 lb		ufacturer (from product label)	A Clean Cigarett
In confidence	24 Years	✓ Male	or kg	#2		
	EVENT, PRODUCT	PROBLEM OR ERR	OR	2. Dose or Amount	Frequency	Route
Check all that apply:  1. Adverse Even		em (e.g., defects/malfunctio		#1		·
<i>~</i>	ted to Adverse Event	Different Manufacturer of	Same Medicine	#2		
(Check all that appl					own, give duration) from/to (or	5. Event Abated After Use
Death:	(mm/dd/yyyy)	Disability or Permaner	nt Damage	best estimate) #1 04/01/2010	08/01/2010	Stopped or Dose Reduced?
Life-threatening		Congenital Anomaly/B	irth Defect	#1 01/02/2010		Appl
		Other Serious (Importa		#2 4. Diagnosis or Reason	for the (Indication)	#2 Yes No Does
Required Interv	vention to Prevent Permar	nent Impairment/Damage (D	Devices)	Help to Stop		8. Event Reappeared After Reintroduction?
<ol> <li>Date of Event (mm 04/01/20</li> </ol>		4. Date of this Report (mr 06/19/2013	m/dd/yyyy)	#1 #2		#1 Yes No Does
5. Describe Event, Po	roblem or Product Use E	Error		6. Lot #	7. Expiration Date	#2 Yes No Does
l	-	Cigarette" b		#1 not specified	1 #1	9. NDC # or Unique ID
		r months, I de		#2	#2	none
		, as well as these problems		E. SUSPECT MED	DICAL DEVICE	
		ter I stopped		1. Brand Name A Clean Cigare	****	
the produc	t.			2. Common Device Nam		
				e-cigarette	Other	
				3. Manufacturer Name, 6 Saginaw, MI	City and State	
				4. Model #	Lot#	5. Operator of Device
				Catalog #	Expiration Date (r	
				Serial #	Other #	Other:
				6. If Implanted, Give Date	te (mm/dd/yyyy) 7. If Ex	planted, Give Date (mm/dd/yyyy)
				8. Is this a Single-use D	evice that was Reprocessed	and Reused on a Patient?
			More		inter Name and Address of F	Reprocessor
6. Relevant Tests/Lai	boratory Data, Including	Dates	-			
	st 2010 MRI ood tests - 1	- August 2010 August 2010	0			
				E OTHER (CONC	OMITANT) MEDICAL	PRODUCTS
					rapy dates (exclude treatmen	
			More			
7. Other Relevant His	story, including Preexist	ting Medical Conditions (ever/kidney problems, etc.)	2000000000	C DEDODTED (C	Con confidentiality and	More
		k a day smoke:	r, rarely	Name and Address	See confidentiality sec	tion on back)
		to common bin		(b) (6)		
		Allergy to po	-			
			More	Phone # (b) (6)	E-mail (b) (	
C. PRODUCT A	VAILABILITY		h-to-schoolsell.	2. Health Professional?		4. Also Reported to:
	r Evaluation? (Do not ser	nd product to FDA)	· ·	Yes 🗸 No		Manufacturer
✓ Yes 🗆 No	Returned to Ma	nufacturer on:		5. If you do NOT want yo	our identity disclosed	User Facility

(mm/dd/yyyy)

The FDA Safety Information and **Adverse Event Reporting Program** A. PATIENT INFORMATION

**EDWATCH** 

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

Internet Submission - Page 1/2

2		
	Form Approved	d: OMB No. 0910-0291, Expires: 10/31/08 See OMB statement on reverse.
Y reporting of		DA USE ONLY
uct problems and	Triage unit	
e errors	sequence #	
- Page 1/3		
D. SUSPECT PROD	UCT(S)	
1. Name, Strength, Manufa 60% VG 40%PG 16 #1nicotine #2	cturer (from product labeling	Vixen Vapors
#2 2. Dose or Amount	Frequency	Route
#1	hourly	
"		Illinai
#2		,
Dates of Use(If unknown, best estimate)	, give duration) from/to (or	5. Event Abated After Use Stopped or Dose Reduced?
#1 06/01/2012	04/02/2013	#1 Yes No Doesn't Apply
#2		#2 Yes No Doesn't
4. Diagnosis or Reason for smoking ceasat #1		8. Event Reappeared After Reintroduction?
#2		#1 Yes No Doesn't Apply
6. Lot #	7. Expiration Date	#2 Yes No Doesn't Apply
#1	#1	9. NDC # or Unique ID
#2	#2	
E. SUSPECT MEDIC	AL DEVICE	
1. Brand Name Vixen Vapors		
2. Common Device Name		
e cigarette ViVi		
3. Manufacturer Name, City	and State	
4. Model #	Lot#	5. Operator of Device
Catalog #	Expiration Date	(mm/dd/yyyy)
Serial #	Other #	Other:
6. If Implanted, Give Date (	mm/dd/yyyy) 7. If E	xplanted, Give Date (mm/dd/yyyy)

	Date of Birth:	ent, or 3.	Sex	4. Weight 179	
(b) (6)	(b) (6)		Female	or =	_lb
In confidence	30 Years		✓ Male		, kg
	EVENT, PRODUC	T PROBL	EM OR ERRO	)R	
Check all that apply:					
1. Adverse Even			efects/malfunction	-	
Product Use E	Frror Problem wi	th Different M	anufacturer of S	ame Medicin	e
2. Outcomes Attribut (Check all that appl	ted to Adverse Event				
(b	(6)			_	
Death:	(mm/dd/yyyy)	Disabi	lity or Permanent	Damage	
Life-threatening		Conge	enital Anomaly/Bir	th Defect	
Hospitalization	- initial or prolonged	Other	Serious (Importar	nt Medical Eve	ents)
Required Inter	vention to Prevent Perr	nanent Impain	ment/Damage (De	evices)	
3. Date of Event (mm	n/dd/vvvy)	4. Date of	this Report (mm	/dd/yyyy)	
(b) (6)		0.5	5/10/2013		
5. Describe Event. P	roblem or Product Us	e Error			
İ					
	an smoking				
	cause they			are. He	9
	the ones t				
	then moved				1
	or in the s the "liqui				
	. He began				
	apor ones b				ar
	s a healthy			one yea	••
(b) (6)	b u neuron,	Journa	#IG11 #110		
	was a healt	hv eate	r. i.e.:	fruit	
	n shakes, s				
etc. About	two weeks	prior t	o his de	ath he	
	ing like he				
Dogum =			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Then it tu			and was	taking	<b>T</b>
	rned into		g and was	taking	3
Then it tu cough medi	rned into		g and was	taking	3
	rned into		g and was	taking	3
	rned into		g and was	taking	3
	rned into		g and was	taking	Ŧ.
	rned into		g and was		
cough medi	rned into o	oughing	g and was	taking	
cough medi	rned into	oughing	g and was		
cough medi	rned into cations. I	oughing		Мо	
cough medi  6. Relevant Tests/La  I am still	rned into o	ing Dates	ıtopsy re	Mo	re
cough medi  6. Relevant Tests/La  I am still	cations. I  boratory Data, Includ	ing Dates	ıtopsy re	Mo	re
6. Relevant Tests/La I am still don't know	cations. I  boratory Data, Includ	ing Dates	ıtopsy re	Mo	re
6. Relevant Tests/La I am still don't know	cations. I  boratory Data, Includ	ing Dates	ıtopsy re	Mo	re
6. Relevant Tests/La I am still don't know	cations. I  boratory Data, Includ	ing Dates	ıtopsy re	Mo	re
6. Relevant Tests/La I am still don't know	cations. I  boratory Data, Includ	ing Dates	ıtopsy re	Mo	re
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6. Relevant Tests/La I am still don't know be tested.	boratory Data, Includ waiting on where to t	ing Dates  a the au take the	ntopsy re	port. I have to	re I
6. Relevant Tests/La I am still don't know be tested.  7. Other Relevant Hir race, pregnancy, sr	boratory Data, Includ waiting on where to t	ing Dates  a the au ake the	atopsy re e oils I	mort. I have to Mo	re I
6. Relevant Tests/La I am still don't know be tested.  7. Other Relevant His race, pregnancy, sr No allergi	boratory Data, Includ waiting on where to t	ing Dates  a the au take the	atopsy re a oils I  al Conditions (e. problems, etc.)	port. I have to	re re
6. Relevant Tests/La I am still don't know be tested.  7. Other Relevant His race, pregnancy, sr No allergi tobacco ci	boratory Data, Includ waiting on where to t	ing Dates  a the au take the disting Medica, liver/kidney, Male. Serer two	al Conditions (e. problems, etc.) Stopped syears ag	port. I have to move the move to move the move t	re re
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6. Relevant Tests/La  I am still don't know be tested.  7. Other Relevant Hir race, pregnancy, sr No allergi tobacco ci cigars the	boratory Data, Includ waiting on where to t  story, Including Pree moking and alcohol use es, White. garettes over	ing Dates  a the au take the disting Medica, liver/kidney, Male. Serer two	al Conditions (e. problems, etc.) Stopped syears ag	mo  port. I  have to  mo  g. allergies,  moking o, ther inking	re
6. Relevant Tests/La  I am still don't know be tested.  7. Other Relevant His race, pregnancy, so No allergi tobacco ci cigars the over one a	boratory Data, Include waiting on where to to story, Including Presmoking and alcohol use es, White. garettes over e cigaret and one	ing Dates  a the au take the disting Medica, liver/kidney, Male. Serer two	al Conditions (e. problems, etc.) Stopped syears ag	port. I have to move the move to move the move t	re
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6. Relevant Tests/La  I am still don't know be tested.  7. Other Relevant His race, pregnancy, sr No allergi tobacco ci cigars the over one a	boratory Data, Include waiting on where to to story, Including Presmoking and alcohol use es, White. garettes over e cigaret and one	ing Dates  a the au take the take the Male. Serer two	al Conditions (e. problems, etc.) Stopped syears agreement of the company of the	mo  port. I  have to  mo  g. allergies,  moking o, ther inking	re

Diagnosis or Reason for		
smoking ceasa		8. Event Reappeared After
#1		Reintroduction?
#2		#1 Yes No Apply
). Lot #	7. Expiration Date	#2 Yes No Doesn
#1	#1	9. NDC # or Unique ID
#2	#2	
E. SUSPECT MEDI  Brand Name Vixen Vapors  Common Device Name	,	
e cigarette ViV . Manufacturer Name, C		
. Model #	Lot #	5. Operator of Device Health Professions
Catalog #	Expiration Date	
Serial #	Other #	Other:
. If Implanted, Give Date	(mm/dd/yyyy) 7. lf	Explanted, Give Date (mm/dd/yyyy)
. Is this a Single-use Dev	vice that was Reprocess	ed and Reused on a Patient?
Yes No	ter Name and Address o	
. If Yes to Item No. 8, En	ter Name and Address o	
. If Yes to Item No. 8, En	ter Name and Address o	Reprocessor
. If Yes to Item No. 8, En	ter Name and Address o  CTU  MAY 1 8 2013  DMITANT) MEDICA	Reprocessor
. If Yes to Item No. 8, En	ter Name and Address o  CTU  MAY 1 8 2013  DMITANT) MEDICA	Reprocessor
F. OTHER (CONCO	ter Name and Address o  CTU  MAY 1 8 2013  DMITANT) MEDICA	I Reprocessor  L PRODUCTS ent of event)
F. OTHER (CONCOProduct names and there	AAY 1 3 2013  DMITANT) MEDICA  apy dates (exclude treatm	I Reprocessor  L PRODUCTS ent of event)
F. OTHER (CONCOProduct names and there G. REPORTER (Se. Name and Address b) (6)	ter Name and Address of CTU  MAY 1 3 2013  DMITANT) MEDICA apy dates (exclude treatment of the confidentiality see confidentiality see	L PRODUCTS ent of event)  More
F. OTHER (CONCOProduct names and there  G. REPORTER (Se. Name and Address b) (6)	ter Name and Address of CTU  MAY 1 3 2013  DMITANT) MEDICA apy dates (exclude treatment of the confidentiality see Confidentia	L PRODUCTS ent of event)  More ection on back)
F. OTHER (CONCOProduct names and there  G. REPORTER (Sec. Name and Address b) (6)	TO CTU  MAY 1 3 2013  DMITANT) MEDICA apy dates (exclude treatments) are confidentiality see confidentiali	PRODUCTS ent of event)  More ection on back)
G. REPORTER (Se. Name and Address b) (6)  hone (b) (6)  Health Professional?	AAY 1 8 2013  DMITANT) MEDICA apy dates (exclude treatment)  See confidentiality see (b)  3. Occupation  Consumer/Non-He	More  ection on back)  More  ection on back)  4. Also Reported to:  Manufacturer
F. OTHER (CONCOProduct names and there  G. REPORTER (Secondary Concording to the con	TO CONSUMER/NON-He ar Identity disclosed	PRODUCTS ent of event)  More ection on back)



#### B5. Describe event or problem continued

begged him to stop smoking those things and let me take him to the doctor. He said "they are just water and flavor and won't harm me." I read up on them and found some are made with oils and antifreeze. I pulled down the kit my son had and opened the two bottles of "liquid" that he inhaled on a consistent basis. I put a small amount on my fingers and it felt just like mineral oil. My son was inhaling antifreeze and mineral oil and was told it was safer than cigarettes. He fell asleep next to me on the couch that night, and I, just thinking he was very tired, covered him up and took the cigarette out of his hand and went to bed, I woke up at 7:40 a.m. to let our dogs out as I did every morning and he was still on the couch. I thought nothing of it at first and was telling him he needed to wake up and go get in bed, When I walked back over to the couch where he was reclined, I noticed something dark brown, like blood or something coming out of his mouth. I FREAKED OUT!!!! I am convinced it was this oil he was heating up in these e cigarettes and inhaling that took my son's life and forever changed mine. He had a doctor's appointment that day at 11:00 to see about his cough. He never made it. I will never be the same.



### B7. Other relevant history, including preexisting medical conditions continued

half years ago. No medical issues known. He has pain in his wrists from massaging, but that is all I know about. I was with him every day and night. Someone needs to put a stop to this industry.

Mail to: MEDWATCH

or FAX to:

1-800-FDA-0178

5600 Fishers Lane Rockville, MD 20852-9787

DORS

U.S. Department of Health and Human Services

(b) ໃ6)

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

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

FDA USE ONLY

IVIED T	W MICH	au		use errors	Triago unit US	3-FDA-200018	·
The FDA Safety I Adverse Event R	Information and Reporting Program	Internet S	ubmission - P	age 1			Access, challenges and access and
A. PATIENT INF	FORMATION			D. SUSPECT PRO	DUCT(S)		
b) (6)	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight	1. Name, Strength, Manual			
		V Female Male	orkg	# E-liquid	32mg	K	OΛ
In confidence	40 Yea VENT, PRODUCT PRO			#2			.,
Check all that apply.		4:-2-A		2. Dose or Amount	Fre	quency	Route
1. Adverse Event	*****	g., defects/mailunch	ons)	#1		and the same of th	
Product Use E		ent Manufacturer of	Same Modicine	#2			
<ol><li>Outcomes Attribut (Check all that apply</li></ol>	ted to Adverse Event y)		1	3. Dates of Use (if unkno best estimate)	wn. give duration) fro	m/lo /e/   5. Even	Abated After Use
Death:	[] a	disability or Permaner	nt Damage		-	3100	oed or Dose Reduced?
Lile-threatening	(mm/dd/yyyy)	Congenital Anomaly/6	linh Defect	#1 01/09/2012	01/19/	2012 #1 🗸	Yes No Doesn't Apply
Hospitalization	- initial or prolonged	Other Serious (Import	ant Medical Events)	42	e e	e2 []	Yes No Docsn't
Required Interv	rantion to Prevent Permanent In	npeirment/Damage (f	Devices)	4. Diagnosis or Reason smoking cass			Reappeared After
3. Date of Event (mm.	*****	te of this Report (m	nvadvyyyy)	#1	Name and address to the second of the second		roduction? Yes No Deasn't
01/19/201		01/22/2012		h5	and a great control of the control o		Apply
	roblem or Product Use Error	<i>5</i> 3	<b>)</b>	6 Lot# NA	7. Expiration 0a	te NS [	Yes No Doesn't
E-Cigarett extreme bl		s of breat	n and	#1	#1	9, NDC	# or Unique ID
CRETCING DI	ouerng.			¥2	12	NA	
	•			E. SUSPECT MED			
				1. Brand Name Knockout Vap			
				2. Common Device Nam E-Cigarettes	ne		
				3. Manufacturer Name, ( Rio Ranch	City and State 10, New Me	exico	
			_	4. Model #	Lot #		S Operator of Device
	RECE	=1\/F-1	)		NA	and the second s	Health Professional
	HEUL	- j A   r		Catalog #	Expiration	n Date (min/dd/yyyy	Lay User/Patient
	JAN S	23 2012		Serial #	Other #		Other:
	MEDWA		ru	6. If implanted, Give Da	te (mm/dd/yyyy)	7. If Explanted, G	ive Date (mm/dd/yyyy)
	WEDWA			8. is this a Single-use D	levice that was Repr	ocessed and Reus	ed on a Patient?
l				9. If Yes to item No. 8, 8	nter Name and Add	ress of Reprocesso	or
6. Relevant Tests/Lai NA	borelory Data, Including Date						
1				F. OTHER (CONC	COMITANT) ME	DICAL PRODU	стѕ
				Product names and the	crapy dates (exclude	tresiment of event)	
1							
İ							
				}			
race, prognancy, sn	story, including Preexisting Name and alcohol use, liver/kit	tney problems, etc.)		G. REPORTER (S	See contidentia	lity section on	back)
	a smcker, but l o regular cigar		ive this	1 N(b) (6)		-	
				(b) (6)			1401 E. ST D.ASS
				Phone #	wa sa sa sa sa sa sa sa sa sa sa sa sa sa	E-mail (b) (6)	alitainin kan kan kan kan kan kan kan kan kan ka
				2. Hesith Professional?	13 Occupation	(D) (G)	4 Also Reported to:
C. PRODUCT A	VAILABILITY r Evaluation? (Do not send pro	duet to EDA1		Yes No	Other Health	Professional	Manufacturer
				5. If you do NOT want y	<u>.i.</u>		User Facility
✓ Yes I No	Beturned to Manufac	durer on:(m	m/dd/yyyy)	to the manufacturer,			Distributor/Importer

ServiceCenter Operator: BMYERS

The ERIC has referred Incident Record IM1910607 [Severity 4/ Priority 4] to the Assignment Group: CTP-OFFICE OF SCIENCE.

Assigned on: 01/07/2013 12:08:30

**Customer: CTP** 

Phone: (b) (6)

The customer has reported the following issue:

- (b) (6) called to complain about the E-Cigarette company Totally Wicked. Her 54 year old brother died suddenly in (b) (6) and before he died he told her mom that he thinks it was because of the e-cigarette. He started using e-cigs two years ago and he was a smoker previously. E-cigs was recommended by his doctor. He was diagnosed with cardio menopause. Once he started using them he started becoming short of breath.
- (b) (6) just wanted to inform us so that we can look into it for other users.

She can be reached at (b) (6) or by email at (b) (6) .

Please log into ServiceCenter or visit non-responsive to view, update, and resolve this incident record.

Best Regards,

The Employee Resource and Information Center

U.S. Department of Health and Human Services





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

Form Approved: OME	No. 0910-0291, Expire	s: 10/31/08
	See OMB statement	OO TOWATED

WED TO ALCH		t use errors	Triage unit	
he FDA Safety Information and deverse Event Reporting Program	Internet Submissi			
A. PATIENT INFORMATION		D. SUSPECT PROD	JUCTIES	
	4 Walaha			h-n
Patient Identifier 2. Age at Time of Event, or 3. Sex	4. Weight	1. Name, Strength, Manufi all types of	D/ E	various
e-cig smoker	ornale or	*1e-cigarettes		
In confidence 55 Years		#2		
B. ADVERSE EVENT, PRODUCT PROBLEM C	DR ERROR	2. Dose or Amount	Frequen	cy Route
Check all that apply:		#1		
l. 🖊 Adverse Event 💮 🖟 Product Problem (e.g., defects		•" L	ـ	
Product Use Error Problem with Different Manufa	cturer of Same Medicine	#2		
. Outcomes Attributed to Adverse Event		<u> </u>		
(Check all that apply)		Dates of Use(if unknown best estimate)	n, give duration) from/to	
Death: Disability or	Permanent Damage	Desi esumate)		Stopped or Dose Reduced?
(mm/dd/yyyy)  Z Life-threatening	Anomaly/Birth Defect	#1		#1 Yes No Doesn't
	us (Important Medical Events)	#2		#2 Yes No Doesn't
		4. Diagnosis or Resson fo	or Use (Indication)	Аррку
Required Intervention to Prevent Permanent Impairment/	Jamagé (Devices)	11		8. Event Reappeared After Reintroduction?
	leport (mm/dd/yyyy)	<u>#1</u>		_
12/01/2012 01/07	/2013	#2		#1 Yes No Doesn't
Describe Event, Problem or Product Use Error		6. Lot #	7. Expiration Date	#2 Yes No Doesn't
	T damalement e	#1 m/a		Аругу
My husband uses e-cigarettes.			#1	9. NDC # or Unique ID
extreme allergy to the smell of		#2	#2	n/a
e-cigarette. When I smell the	•	E. SUSPECT MEDI	CAL DEVICE	
NOT odor free- I immediately grand my sinuses begin to ache.		1. Brand Name		
hour my voice go hoarse. With		various		
	ease help get	2. Common Device Name		
these bad products off of the		a-cigaretta 3. Manufecturer Name, Cl	tu and State	
can't get my husband to quit u		various	ny and same	
hazardous products, he will on		Various		
they are banned.	-, <del>-</del>	4. Model #	Lot #	5. Operator of Device
			n/a	Health Professional
		Catalog #	Expiration Da	le (mm/dd/ww)
				Lay User/Patient
		Serial #	Other #	Other:
		6. If Implanted, Give Date	(mm/dd/yyyy) 7. l	f Explanted, Give Data (mm/dd/yyyy)
			vice that was Reproces	sed and Reused on a Patient?
		Yes No		
	More	9. If Yes to Item No. 8, En	ter Name and Address	of Reprocessor
	<u> </u>	4		
6. Relevant Tests/Laboratory Data, including Dates				
		1 1		
		F. OTHER (CONC	DMITANT) MEDIC	AL PRODUCTS
		Product names and then		
		1		
	More			Te discovering to the co
7. Other Relevant History, Including Preexisting Medical Co				alom a
race, pregnancy, smoking and alcohol use, liver/kidney proble	erns, etc.)	G. REPORTER (Se	ee confidentiality	section on back)
There was no death or hospital	ization for	1. Name and Address	tanti aliferi	
this input, but I could not su	bmit this form			
unless I checked that box.				
•			98D*	<u></u>
		Phone #	F.	mail
	fore	<u> </u>		
C. PRODUCT AVAILABILITY		2. Health Professional?	3. Occupation	4. Also Reported to:
Product Available for Evaluation? (Do not send product to FD	A)	Yes 2 No	Consumer/Non-H	lealth Manufacturer
		5. If you do NOT want yo	ur identity disclosed	✓ User Facility
Yes No Returned to Manufacturer on:	(mm/dd/yyyy)		lace an "X" in this box	Distributor/Importer

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 19/31/08 See OMB statement on reverse

## **EDWATCH**

For VOLUNTARY reporting of adverse events, product problems and product use errors Internet Submission - Page 1

	FDA USE ONLY
Friage unit sequence #	

The FDA Safety Information and Adverse Event Reporting Program D. SUSPECT PRODUCT(S) PATIENT INFORMATION 1. Name, Strength, Manufacturer (from product label) 2. Age at Time of Event, or 3. Sex 4. Weight e-liquid 1 Patient identifier Dekang Date of Birth: Female 51.5 Male In confidence B. ADVERSE EVENT. PRODUCT PROBLEM OR ERROR Route Dose or Amount Frequency Check all that apply #1 6mg/30ml Inhal 1. Adverse Event Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine Product Use Error Outcomes Attributed to Adverse Event 3. Dates of Use(If unknown, give duration) from/to (or best estimate) 5. Event Abated After Use (Check all that apply) Stopped or Dose Reduced? Disability or Permanent Damage #1 Yes No Doesn't Death: #1 01/10/2013 01/13/2013 (mm/dd/yyyy) Congenital Anomaly/Birth Defect Life-threatening #2 Yes No Doesn' Other Serious (Important Medical Events) Hospitalization - initial or prolonged 4. Diagnosis or Reason for Use (Indication) Required intervention to Prevent Permanent Impairment/Damage (Devices) 8. Event Reappeared After Rash Reintroduction? #1 4. Date of this Report (mm/dd/yyyy) 3. Date of Event (mm/dd/yyyy) #1 Yes No Doesn 01/13/2013 01/12/2013 #2 #2 Yes No Doesn' 6 Lot# 7. Expiration Date 5. Describe Event, Problem or Product Use Error No Lot 12 hours after inhalated a 6mg vanilla dose 9. NDC # or Unique ID of electronic cigarretes, the patient had a #2 42 rash on her left and right arm. The left arm E. SUSPECT MEDICAL DEVICE rash covered from the wrist to the elbow, while the right arm covered just the wrist. ELECTRONIC CIGARRETE Also she was not able to talk well, her 2. Common Device Name throat was closed. The patient did not JLS e-cigarrate 3. Manufacturer Name, City and State relate the rash to the electronic cigarrete substance, so the next day, she smoked Comercializadora JLS México Salamanca 73, Col. Roma, Mexico Distrito Federal, Mexico, CP. 06700 again, but the rash extended to her abdomen, 5. Operator of Device 4. Model # Lot # the back, and the cheeks. Also the throat vapErs-GoU 650 mAh was completely closed, and she was not able Health Professional Catalog # Expiration Date (mm/dd/yyyy) to talk. After 12 hours without smoking, Lay User/Patient the throat began to open again. No Other: Other # medications were administered during the Serial # reaction, or 5. If implented, 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 Z No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor Hore 6. Relevant Tests/Laboratory Data, Including Dates None F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) NA More More Other Relevant History, Including Prexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) G. REPORTER (See confidentiality section on back) I. Name and Address Smoking: Camel Previous e-cigarrete brand JLS 11mg, blueberry -no reactions occuredduring 1 week prior to the rash. E-mail More 2. Health Professional? 3. Occupation 4. Also Reported to: C. PRODUCT AVAILABILITY Other Health Yes No Manufacturer Product Available for Evaluation? (Do not send product to FDA) User Facility 5. If you do NOT want your identity disclosed Yes Z No Returned to Manufacturer on: \_ Distributor/Import to the manufacturer, place an "X" in this box: (mm/dd/yyyy)



B5. Describe event or problem continued

before the reaction.

Mail to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787 1-800-FDA-0178

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

### MEDWATCH

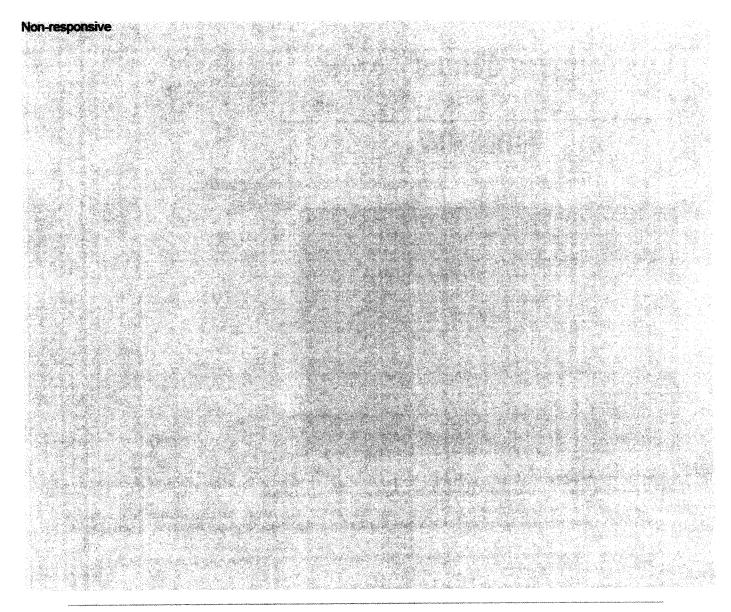
The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

	FDA USE ONLY	
Triage unit		
sequence #		

	countries	, 				CHEREST BRO	200	(0)				
A. PATIENT INF			- •	- 100-1-4m		SUSPECT PRO	_	· · · · · ·		.n		
1	2. Age at Time of Even Date of Birth:	A, or	3. Sex	4. Weight 245 b		ame, Strength, Manu Blectronic	ITECTURE	a (júbii h	roduct inve	7	<b>:</b>	
*pouce			∐ Female  ✓ Male	or		Cigarettes						
In confidence			4	кд	#2							
	VENT, PRODUCT	PROB	LENI OR ERRO	DR	2.	Dose or Amount			Frequenc	y	Rout	No
Check all that apply:	,				#1				<u> </u>	•	$\neg \vdash$	
1. Adverse Event	protein		defects/malfunction	1	*'							
Product Dee E	rror Problem with	Different	Manufacturer of S	ame Medicine	#2							
2. Outcomes Attribut												
(Check all that appl)	"	_			3. 0	<b>Pates of Use</b> (If unimo: rest estimate)	wn, give	duration)	) trom/to (o		t Abated Aft ped or Dose	
Death:	(mm/dd/yyyy)	. L. Disa	ibility or Permanent	Damage	#1						Yes No	n Doesn't
Life-threatening		Con	genital Anomaly/Bir	th Defect	==	<del></del>				-		Apply
Hospitalization	- initial or prolonged	Othe	er Serious (Importer	nt Medical Events)	#2	1				#2	Yes 🔲 No	o Doesn't
Required Interv	ention to Prevent Perma	nent Impa	iment/Damage (Dr	avices)	4. D	iagnosis or Resson i	for Use	(Indicatio	on)	8. Even	1 Reappears	
3. Dete of Event (mm	·····		of this Report (mm		#1						reduction?	•
S. Date Of Event (IIII)	,00 yyyy	1	01/21/2013	,00,7,7,7	#2					_  #1 🗀	Yes 🗌 No	o Doesn't Apply
S. Donnelle Sunne De	white or Deadwet Han	L			6. L		77 5	xpiration	Data			C Donen's
•	roblem or Product Use i						/. E	KPIFECION	Des	#2	Yes No	Apply
	e been aroun				#1	?	#1			9. NDC	# or Unique	ID
	Cigarettes				#2		#2			7		
	d a second t					SUSPECT MED		DEVIC	E			
	around regul	ar cı	garettes	this has	_	rand Name	.07.	021.0	-	******		
also happe	nea.					lectronic Cig	arett	68				
						ommon Device Nam						
						lactronic Ciga						
					3. 7	lanufacturer Name, C	.ay ano	3(816				
					'							
					4. M	lodel#		Lot #			5. Operat	tor of Device
								?			1	th Professional
					C	atalog #		Expira	ntion Date	(mm/dd/yyyy		
						•				V	Lay	User/Patient
				l	S	erial #		Other	•	<del></del>	Othe	9r:
										-	L	<del></del>
					6. H	Implanted, Give Date	e (mm/d	(d/yyyy)	7. If E	xplanted, G	ive Date (m	m/dd/yyyy)
						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			1			
					8. Ja	this a Single-use De	avice th	at was R	eprocess	d and Reuse	ed on a Pati	ient?
						Yes No						
				More	9. #	Yes to Item No. 8, E	nter Nar	me and A	ddress of	Reprocesso	×	
	<b>5.1.1.4</b>											
5. Helevant Tests/Lab	boratory Data, Including	) Dates										
					F.	OTHER (CONC	OMITA	ANT) M	EDICAL	PRODUC	CTS	
						duct names and ther						
				l	1	did not use	this	produc	et but	a friend	did an	id I
				I		as sick for a						-
***				<b>X</b> SAN								
7. Other Relevant Historical International States	tory, Including Preexist noking and alcohol use, li	ting Medi	cal Conditions (e.g	g., allergies,		DEBORTED (C						More
	-	,	( proments, en.,)	1		REPORTER (S	ee coi	nlideni	iality se	ection on .	ba <b>c</b> k)	
White seld	dom use alco	hol			1. N	ame and Address	PCS OOX					
				I	Z Trunkin	en Nassan agen in in in in in in in in in in in in in	3 (S)				0.788-088-038	
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				Ecro	Pho	ne #			E-ma	<b>il</b>	nericens comme	
C DROBHCT AN	VALLADILITY			Braintechnolle of	2 H	salth Professional?	3 000	unation			4. Also Rep	orted to:
C. PRODUCT AV	Evaluation? (Do not see		14n CD41				l	•	Non-Hea	1	_	
Product Available for	EVERUETION / (DO NOT SE	на рповис	TRO FUA)	I		Yes My No	<u></u>			17.611	Manuf	
Yes Z No	Returned to Ma	inufacture	r on:			you do NOT want yo						Facility
			(mm/i	(dd/yyyy)	10	the manufacturer, p	lace an	"X" in th	iis box:		Distric	butor/Importer



From: (b) (6)

**Sent:** Sunday, January 22, 2012 4:41 PM

To: AskCTP
Subject:

can you check into electronic ciggaretts causing

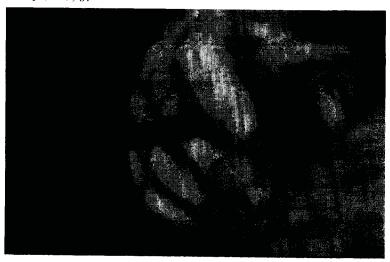
pleurisy

i magicly have it after starting electronic ciggaretts

# Los Angeles Times NATION

## **NATION NOW**

Are smokeless cigarettes safer? E-cig explodes in smoker's mouth February 16, 2012 + 9:54 am



Electronic cigarettes and cigars are billed as a safer way to get a nicotine high, but a Florida man learned just how dangerous they can be this week. One of the devices exploded in his mouth, ripping out part of his tongue and several teeth while badly burning his face.

"He is very, very lucky," Fire Chief Joseph Miller of the North Bay Fire Control District told The Times. The man, identified as Tom Holloway, 57, was taken to a local hospital for treatment Wednesday, then transported to an Alabama hospital that specializes in burns. He has since been released. "It could have been a lot worse," Miller added.

Emergency responders said the device that Holloway was holding in his mouth acted like "a bottle rocket." Holloway was in his home office at the time, and some carpet and chair cushions also burned.

Electronic cigarettes and cigars — commonly called e-cigarettes and e-cigars — are all the rage even though their safety is hotly debated. They use a nicotine cartridge and a battery. The battery creates an electrical charge that releases the nicotine vapor. The user inhales that familiar shot of nicotine, without the smoke.

Until now, controversy has largely centered on federal regulatory issues and whether consumers are being misled by a device that some say could actually be more toxic than regular cigarettes because of the secondary chemicals used. But this week's explosion will obviously raise more immediate safety questions.

As you might imagine, the incident -- and ensuing publicity -- isn't good P.R. for the burgeoning industry of smokeless cigarettes and cigars.

Thomas Kiklas, co-founder of the Tobacco Vapor Electronic Cigarette Assn. told The Times that he believes the device that Holloway used was not the commonly sold kind, but a specially modified device designed to give the user a turbo-charged blast of nicotine. (He likened it to the difference between a push lawn mower and a gasoline-charged lawnmower.) He said on his site that it is too soon to jump to any conclusion about possible product failure.

Miller, the Niceville, Fla.-based fire chief, said he'd never heard of the device before, but assumes that it was a one-time fluke. "When I heard 'electronic cigarette,' I said, 'What in the heck is that?' "

The injured man has since called to thank the emergency responders for their quick action. "He was very, very thankful."

#### ALSO

At Heart Attack Grill, diner's symptoms weren't fake

Josh Powell won't be buried next to sons; officers buy plots

New Jersey expected to approve gay marriage; Christie vows veto

-- Rene Lynch

Twitter / renelynch

File photo: An e-cigarette. Credit: Gerry Broome / Associated Press

(b) (6)

Nice to talk with you today. I have a number of pictures but am unsure how to send all in one email so I will send them separately (1 picture/ email). The resolution of these pictures are not great but the whitish areas in the changed gingiva are actually areas of denuded bone.

(b) (6)

Today, I received an interesting call from a local dentist who saw the article on e-cigs and thus got my name. She told me said she has a current patient who has been a long term user of the e-cigarette who had significant pathology in his oral mucosa that she believes was caused by the e-cigarette. It makes sense that if there are side effects associated with using e-cigs that they would be found in the mouth. However, I have not previously heard of problems with destroying oral tissue in the mouth linked to e-cigarettes. However, it makes sense that dental professionals would be the first to observe adverse consequences if there are any.

I advised the dentists who called me to do two things: 1) write up a case study on her observations with this patient (she sent me pictures which are attached) so her dental colleagues might be alerted to this potential adverse consequence; and 2) submit an adverse event report to FDA.

I told her I would take care of the later so consider this note to be the adverse event report since I'm not sure if there is a formal way to do this for tobacco products under FDAs authority. The attachment which includes the e-mail I received includes the dentist's name and contact information so perhaps you can have someone speak with her directly. She seemed very credible. The patient is coming back to see her so there would be an opportunity to asses if the pathology changes with discontinuation of the ecig. She told me the patient is a bit compulsive and has been using the e-cig continuously.

(b) (6)

Professor,
Department of Psychiatry & Behavioral Sciences
Medical University of South Carolina

3/4/12

To The FDA

To Whom it may concern

I feel I need to inform you guys, I have had a real bad experience with The E Cigarette. About A month ago I decided to try and quit or at least cut down on tobacco, so I purchased the

The brand was called VapCigs, VC Plus.

I used them on a moderate basis, nothing excessive, The first week, my cravings seemed to be under control.

Around the second week I noticed some changes, with my appearance, my skin on my face was like I had gotten a real bad sunburn and the skin on my legs and arms was real rough, almost scaly. And very itchy, but hurt to touch.

I did not link this to the E-cigarette at the time.

Around the 3rd week, I started getting very sharp pains across my chest and some very bad headaches, and my blood pressure was starting to get very high, but my heart rate was low for

Since this E-Cig was the only thing new in my life style I felt I needed to stop using the product. This is the 4th week, My skin is getting better and the pains in my chest have gone now, I am not in the frame of health, as before I started The E-Cig, but seem to be getting there.

I really think you all need to take a look at the product, for safety reasons at least.

Thank for heing there.
(b) (6)

## MEDWATCH

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

Form Approved: OMB No. 0910-0291, Expire See OMB statement	
FDA USE ONLY	

Triage unit US-FDA-205000 sequence #

_	Information and leporting Program	Internet Su	bmission - P	age 1					
A. PATIENT INF				D. SUSPEC	T PRODUCT	(S)			
	2. Age at Time of Event, of	r 3. Sex	4. Weight		th, Manufacture		label)		
6)	Date of Birth:	Female	220 lb	, NJoy					
In confidence	(b) (6)	Male	orkg	<b>82</b>				-	
B. ADVERSE E	VENT. PRODUCT P	ROBLEM OR ERR	PAC	2. Dose or A	mount	Fraqu	ency	Route	
check all that apply:			1	"I pu	ff	7 20	puffs		-
Adverse Even	=	(e.g., defects/malfunction		"		<u> </u>			
Product Use E		ferent Manufacturer of S	iame Medicine	#2		][			
<ul> <li>Outcomes Attribut</li> <li>(Check all that appl)</li> </ul>	ted to Adverse Event by)			3. Dates of Use	(Il unknown, give	duration) from/	to (or   5. Ever	nt Abated Afte	r Use
Death:	-	Disability or Permanen	Damage	best estimate	j 1 Wee	kto	0.00	pped or Dose F	Reduced?
Life-threatening	(mm/dd/yyyy)	Congenital Anomaly/Bi	dh Delect	#1			*'	Yes No	Apply
	u - initial or prolonged	Other Serious (Importa	I I	#2	••		#2	Yes No	Doesn't
= '	vention to Prevent Permane	_	1		Reason for Use	(Indication)	A FVA	nt Reappeared	Apply
. Date of Event (mm	<del></del>	Date of this Report (mn		#1	g cesation			troduction?	
03/10/201		04/12/2012	,,,,,	#2			#1 [	Yes No	Doesn't Apply
. Describe Event. P	roblem or Product Use Err			5. Lot #	7. Ex	piration Date	12 [	Yes No	Doesn't
•	ng a drag sta		seeing	#1	#1				Apply
dots urin	ating on self	when coughing	ng stop	#1			9. NDC	a or Unique II	U
	gasping for		5			DEVICE			
minutes fo	or attack to s	top		1. Brand Name	CT MEDICAL	DEVICE		<u> </u>	
				T. BISTO NUMBER					
				2. Common De	vice Name				
				3. Manufacture	r Name, City and	State	<del></del>		
					•				
								7	
				4. Model ∉		Lot#		5. Operato	
				Catalog #		Expiration	Date (mm/dd/yyy	N/I	n Professional
								Lay U	ser/Patient
				Serial #		Other #		Other	
					51 - 5 - 1 - 1	10		C'- 0-4-	
				5. If implanted	, Give Date (mm/c	יאניניסו	7. If Explanted, (	CIVE DRIES (CHIC)	υσαγγγγ)
				6. Is this a Sin	gle-use Device th	at was Repro	essed and Reu	sed on a Patie	nt?
				Yes	☐ No	· · · · · · · · · · · · · · · · · · ·			
				9. If Yes to Iter	n No. 8, Enter Na	me and Addre	as of Reprocess	sor	
5. Relevant Tests/La	aboratory Data, including i	Jates							
				E OTHER	(CONCOMIT	ANT) MEDI	CAL PRODI	ICTS	
				Product name	s and therapy da	tee (exclude tr	eatment of event	))	
				1	tramado	hydro	codone	carbamz	epine
				klonopi	.π				~
				1					
7. Other Referent M	istory, including Presxisti	as Madical Conditions (	o allemne	! [					
race, pregnancy, s	imoking and alcohol use, livi	ar/kidney problems, etc.)		G. REPOR	TER (See co	nfidentiali	y section or	n back)	
	gia back pair	bipolar a	nxiety	1. N(b) (6)	l cicira a a	9.752 <del>8.</del> 553			
disorder				(-,,,,,,,,,					
				(b) (6)			<b>4</b> 668 55		
							E-mail		urici <u> </u>
				Phone # (b)	(6)		(b) (6)		11 243 14
C. PRODUCT	AVAILABILITY			2. Health Prof	essional? 3. Oc	cupation		4. Also Repo	orted to:
	or Evaluation? (Do not sen	d product to FDA)		☐ Yes {	_ No			Manuf	acturer
✓ Yes □ N	No Returned to Mar	udactivar on:		5. If you do N	OT want your idea	utty disclosed		User F	
Yes N	An [""] Listninger to With	Imi	n/dd/www)	to the manu	sfacturer, place a	n "X" in this b	ox:	Distrib	utor/importer



# MED**W**ATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems Internet Submission - Page 6

Drug	Manufacture	Dose	e Unit	Route	Dosag	Frequence Interva	y I Unit	Is Con- comita
				<u> </u>				
<del></del>						<u> </u>	ļ	+
				l		<u> </u>	<u> </u>	
Diagnosis	for Use	Start	End	Duration	Unit			
	101 000	Date	Date	- Juliunoli				
<del></del>								
DAMWVOLUNTARY_205(	2012-04-13-07.47.0 000_17216_20120412.xr : Paper	7  ***** nl	***				······································	-

Mail to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787

1-800-FDA-0178

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

U.S. Department of Health and Human Services

### MEDWATCH

B. ADVERSE EVENT, PRODUCT PHO

2. Outcomes Attributed to Adverse Event

Hospitalization - initial or prolonged

take this stuff off

6. Relevant Tests/Laboratory Data, Including Dates

5. Describe Event, Problem or Product Use Error

Date of Birth:

(mm/dd/yyyy)

Required intervention to Prevent Permanent Impairment/Damage (Devices)

The product name is lava it is the potpurri that many people are smoking my boyfriend is smoking it and it has cause some serious problems it has cause him memory loss, seizures, he can not speak or walk when he is smoking this stuff he has became very very addicted to this lava im very concered with what it is doing to him. I really woulkd like this stuff to be banned and taken off the shelves of the stores... The store that he keeps buying it from is Exxon Mobile and the adress is, (b) (6)
And there phone humber is (b) (6) Please i am begg you to please help me and everyone else

20 Yea

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION 1. Patient identifier 2. Age at Time of Event, or

In confidence

Check all that apply 1. Adverse Event

(Check all that apply)

Life threatening

3. Date of Event (mm/dd/yyyy) 04/02/2012

Death: \_\_\_

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

Internet Submission - Pa

4. Weight

122

Sex

Product Problem (e.g., delects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine

Female

**ELEM OK ERROI** 

Disability or Permanent Damage

Congonital Anomaly/Birth Defect

4. Date of this Report (mm/do/yyyy)

Please i am begging

RECEIVED

MAY 07 2012

**MEDWATCH CTU** 

(mm/dd/yyyy)

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

Returned to Manufacturer on: \_\_\_

05/05/2012

Other Serious (Important Medical Events)

Male

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

FDA USE ONLY

Triage unil US-FDA-206274 sequence #

ge 1						
D. SUSPECT PROD						
1. Name, Strength, Manufa		<i>productiabel)</i> a streno	ih Ma	ade in USA		
<u> </u>			1.16	ide in oon		
#2 2. Dose or Amount		Frequency		Route		
3 grams		T TOQUESTIC)		TOUR TOUR		
112			ta yer anala sedakiyayini			
3. Dates of Use(If unknown best estimate)	, givo duratio	n) from/to (or		Abated After Use ed or Dose Reduced?		
#1	**		#1   Y	es No Deesn't		
#2				Apply Ta Doesn't		
4. Diagnosis or Reason for	Use (Indical	tion)	#2 Y	Uppiy		
#1			Reintro	Reappeared After oduction?		
#2			WI Y	es No 🔽 Doesn't		
6. Lot #	7. Expiratio	n Date	#2 Y	es No Poesn't		
#1 3621171146	#1		9 NOC #	or Unique ID		
#2	#2		36211	71146		
E. SUSPECT MEDIC	AL DEVI	CE	1.			
1. Brand Name						
2. Common Device Name						
3. Manufacturer Name, City	y and State	CONTRACTOR OF THE SALE OF				
4. Model #	Lot	ı		5. Operator of Device		
Catalog #	Expi	ration Date (m	ate (mm/sid/yyyy)			
	•	,,,		Lay User/Patient		
Serial #	Othe 3621	er# .171146		Other.		
6. If implanted, Give Date (	mm/dd/yyyy)	7. If Exp	lanted, Giv	e Date (mm/dd/yyyy)		
6. Is this a Single-use Devi	no that was	Reprocessed	and Rauses	t on a Patient?		
Yes No	ce (iii) was	rieprocessen	1114 / 1111/1941	a on a Fondite:		
9. If Yes to Item No. 8, Ente	r Name and	Address of Re	processor			
E OTUCE (CONSO	N117 A N172	MEDIOAL	the child	70		
F. OTHER (CONCO Product names and therap				15		
G. REPORTER (See	e confide	ntiality sec	ien en l	rack)		
1. Name and Address (b) (6)		grafija kanasii ka		,		
(HA)						
				(b) (6)		
Phone #	389638647.64. <u> </u>	E-mail				
(b) (6) 2. Health Professional? 3	Occupation	(b	) (6) <sub>[4</sub>	Also Reported to:		
Yes No				Manufacturer		
5. If you do NOT want you				User Facility		
to the manufacturer, pla	ce an "X" In	this box:		Distributor/Importer		

Yes No

C. PRODUCT AVAILABILITY

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



US-FDA-206274

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

### B5. Describe event or problem continued

he shelves before i lose my boyfriend. He is not the same person i need help and everyone else that smokes this stuff i hear stories about it... It is really scaring me bad i need help for this before my Daughters Father is brain Dead or has altimerz he has became very addicted to this stuff its rediculous

Mail to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787 1-800-FDA-0178

The FDA Safety Information and

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

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

Internet Submission - Page 1

	FDA USE ONLY	
riage unit sequence #	US-FDA-206359	

Adverse Event Reporting Program	n Internet Submission - Pa	#ge 1				
A. PATIENT INFORMATION		D. SUSPECT PRO				
1. Patient identifier 2. Age at Time of Everescue 9.1.1 Date of Birth:	1 200	1. Name, Strength, Men Prosmoke e-	ulacturer (Irom p	roduct iabei)		
rescues 11 Date of Birth: (b) (6)	Female 180 to	#1 cigarette				
in confidence	M Mare KO	#2				
B. ADVERSE EVENT, PRODUCT Check all that apply:	PROBLEM OR ERROR	2. Dose or Amount		Frequency		Route
	blem (e.g., defects/mailunctions)	#1		daily		The state of the s
<u> </u>	Different Manufacturer of Same Medicine	02			And the Advance of the Advance of	
. Outcomes Attributed to Adverse Event				<u> </u>		
(Check all that apply)		3. Dates of Use(If unknown best estimate)	own, give duration	) from/to (or		Abated After Use of or Dose Reduced?
Death:	_ Disability or Permanent Damage	03/01/2012	- 05/0	7/2012	A-11-11-11	es No Doesn't
Life-threatening	Congenital Anomaly/Birth Detect		<u>.                                    </u>			Apply Doesn't
Hospitalization - initial or prolonged	Other Serious (Important Medical Events)	#2	for the Madical		#2   Y	es No Apply
Required Intervention to Prevent Perm	anent Impairment/Damage (Devices)	4 Diagnosis or Reason stop smokin		on)		Reappeared After
Date of Event (mm/ad/yyyy)	4. Date of this Report (mm/dd/yyyy)	#1		<del></del>		es No Doesn's
	05/07/2012	#2			J	Apply
. Describe Event, Problem or Product Use	i i	6. Lot#	7. Expiration	n Date	#2 TY	es No Doesn't
Every since i began u		#1	<u>#1</u>		9. NDC #	or Unique ID
electronic cigarette, bleeding. I was wonde	my gums have started	#2	#2			
reorts of this happen		E. SUSPECT ME	DICAL DEVIC	CE		
ration or crien implies	<i>J</i> ·	1. Brand Name prosmoke				
			700			
		2. Common Device Name cigarette				
		3. Manufacturer Name,	City and State			
		4. Model #	Lot #			5. Operator of Device
						Health Prolessional
		Catalog #	Expl	ration Date (m	m/dd/yyyy)	Lay User/Patient
		Serial #	Othe			Other.
		30/14 W	0	•		
		6. If Implanted, Give Di	te (mm/dd/yyyy)	7. If Ex	planted, Giv	re Date (mm/dd/yyyy)
		8. Is this a Single-use	Device that was	Heprocessed	and Heuse	3 on a Patient?
		9. If Yes to Item No. 8,	Enter Name and	Address of R	eprocessor	
3. Relevant Yests/Laboratory Data, Include	ng Dates					
			0014174	MEDIA	0000	70
	ļ	F. OTHER (CON Product names and th	<u></u>			15
		Product names and th	many nates (exc	ngge neaunen		
	,					
<ol> <li>Other Relevant History, Including Preex race, pregnancy, smoking and alcohol use</li> </ol>	klating Medical Conditions (e.g., allergies, p, liver/kidney problems, etc.)	G. REPORTER	See confide	ntiality sec	tion on b	pack)
none		A Name and Address.	Salatar			
		""(b) (6)				
		TO THE WASHINGTON TOWN WOLLD STORE STORE AND A STORE OF THE STORE	and Market (Strike Skiller and Skiller)	edeka karaga an ini dalah siste	and the	
		(b) (6)				
		Phone # (b) (6)		E-meii (b	(6)	
C. PRODUCT AVAILABILITY		2. Health Professional	7 3. Occupation		14	Also Reported to:
Product Available for Evaluation? (Do not	send product to FDA)	☐ Yes 🕢 No	1			Manufacturer
	·	5. If you do NOT want	your identity dis	closed		User Facility
Yes No Returned to	Manufacturer on:	to the manufactures				Distributor/Importer



US-FDA-206359

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

Internet Submission - Page 6

Drug	Manufacturer	Dose	Unit	Route	Dosage	requency Interval	y Unit	is Con- comitan
					<u> </u>		<del></del>	
		<del> </del>	+	<u>.</u>			·	
						ĺ		

Diagnosis for Use	Start Date	End Date	Duration	Unit

### **FDA Comments:**

WALKERC:   ********   2012-05-08-08.39.55 USFDAMWVOLUNTARY_206359_18373_20120508.xml Route To: Misc. : Paper Center for Tobacco Products Item	,	

Mail to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787

1-800-FDA-0178



# CTP (center for tobacco products)

Triage unit sequence #

U.S. Department of Health and Human Services

### MEDWATCH

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

Form Approved.	OMB No. 0910-0291, Expire	s 10/31/00
	See OMB statement	on reverse

FDA USE ONLY

	Information and Reporting Program	Inter	net Submission	n - Page 1		y diguesco y mago discono discono montro condi menodo co s	
A. PATIENT INF		-		D. SUSPECT PRO	DUCT(S)		
	2. Age at Time of Event, or	3. Sex	4. Weight	1. Name, Strength, Manu	lacturer (from product label)	ine acl	eancigarette.co
(b)	(b) (6) ""	Female	b	Electronic			
In confidence	\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*	Male	or kg	*2	and the same of th		
	VENT, PRODUCT PRO	BLEM OR ERF	ROR	2 Dose or Amount	Frequency		Route
Check all that apply					QIO		16
1. Adverse Even	nt Product Problem (e	g., defects/malfuncti	ons)	el 1 puff			Inhal
Product Use E		ent Manufacturer of	Same Modicine	42			
	ted to Adverse Event	weed to all a contact a transfer of a contact of the contact of th		2. Dates of the // woken	wn, give duration) trom/to (or	5 Event Ah	ated After Use
(Check all that appl				best estimate)	ent, give carrances, itomoto to		or Dose Reduced?
Doath	(mm/dd/vyvy)	Disability or Permane	nt Damage	#1 06/07/2012	06/29/2012	#1 Yes	No Doesn't
Life-threatenin	g [] (	Congenital Anomaly/i	Birth Defect	control control of the control of th	Market and the second s		Duesn't
Hospitalization	- initial or prolonged	Other Serious (Impor	tant Medical Events)	#7	In a line (tradential)	#2 Yes	No Apply
✓ Required Inter	vention to Prevent Permanent It	mpairment/Damage (	Devices)	4. Diagnosis or Reason Smoking Cess			eappeared After
3. Date of Event (mn	n/dd/yyyy) 4. Da	ate of this Report (n	nm/dd/yyyy)	#1		Reintrod	zero et el Dinomole
06/29/20		06/29/2012		#2		T. L.1 Yes	Apply
	Problem or Product Use Error	, group, and a second company of the 1984 (1984)		6. Lot #	7. Expiration Date	#2 Yes	No Doesn't
	2012, patient re	morted as	ahina				мирау
on 06/07/2	2012, patient re ng an e-cigarett	e or Riect	ronic	#1	# *	9 NDC # or	onique io
Misstine F	ng an e-cigarett Delievery System	ENDS- P	oduct	#2	#7		
distribute	ed by www.aclear	cigarette	com. The	E. SUSPECT MED	ICAL DEVICE		
nicotine c	concentration wa	s 24mg -2.	4%/mL-per	1. Brand Name acleancigarett	A 500		
cartridge.	. She described	the coughi	ing	2. Common Device Nam	Company and the second	, the say angular and a second of the second	The second code - Major Constitution of the Committee of the
similar to	o an asthma atta	ick. The co	oughing		tine delivery sy	stem - ENDS	- or
associated	d with puffing o	on the ENDS	3	3. Manufacturer Name,	City and State		
continued	over the durati	ion of 3 we	eks after	acleancigarett	com		
starting t	this product. Th	e patient	was	A A I - A - I - II	Lot#		Operator of Device
notified t	to discontinue t	he product	on	4. Model #	FOI #	i	
06/29/2013	2. This writer o	contacted t	the	Catalog #	Expiration Date		Health Professional
distribute	or on 06/29/2012	to confi	rmed that	Caratog	CAPITOTIC TOTAL	(	Lay User/Patient
the produc	ct contained veg been implicated	decapte Atl	ycerine	Serial #	Other #		Other
which has	-see article by	McCanler	rar y		E-B-	100	
broplems .	-see arricle by	Mccaurey		6. If Implanted, Give Da	le (mm/dd/yyyy) 7. If E	explanted, Give	Date (mm/dd/yyyy)
ļ							
					evice that was Reprocesse	ad and Reused	on a Patient?
i				Yes V No	and the second s		
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6. Relevant Tests/L	aboratory Data, Including Dat	0s					
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					COMITANT) MEDICA		S
				Product names and th	erapy dates (exclude treatm	ent of event)	
			More				<del></del>
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race, pregnancy,	History, Including Preexisting smoking and alcohol use. iivor/i	kidney problems, etc.	)	G. REPORTER (	See confidentiality s	ection on ba	ack)
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disorder.	hypertension,	=					
	- ·		f	Phone !	53	) (6)	
			More	(D) (O) 2. Health Professional		-	Also Reported to:
	AVAILABILITY					4.	
Product Available	for Evaluation? (Do not send p	product to FDA)		✓ Yes No	Pharmacist		Manufacturer User Facility
Yes 🗸	No Returned to Manua	acturer on			your identity disclosed	471	Distributor/Importer
1 , 105 1/1	140 EDECEMBED TO MIGROR		mm/dd/yyyy)	to the manufacturer	place an "X" in this box:		W. I Distributorimporter



### B5. Describe event or problem continued

L. Chest 2012;141-4-:1110-113-. The distribitor also admitted that an undisclosed number of clients had reported "allergic reactions" -no details- to the product.

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

or FAX to: 1-800-FDA-0178

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



### B7. Other relevant history, including preexisting medical conditions continued

hyperlipidemia, Barrett's Esophagitis, GERD, Diabetes, type 2, Obesity, Chronic lower back pain.

Mail to: MEDWATCH

or FAX to:

1-800-FDA-0178

5600 Fishers Lane Rockville, MD 20852-9787

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

CTP

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

# MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1 /1

	FDA	USE ONL	Υ	
Triage unit				
sequence #				

A. PATIENT IN					D. S	USPECT PRO	DUCT(S)					
1	Age at Time of Ever     Date of Birth:	general		4. Weight	1. Nan	e, Strength, Manut emium Electr	acturer (from	product (abel)	Þ	remi	1100	
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In confidence	(b) (6)			kg	#2							
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(Check all that app	ly)					es of Use(if unknow estimate)	n, give duratio	n) from/to (or	5 Event			
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Hospitalization	- initial or prolonged	✓ Other Series	ious (Importa	nt Medical Events)	#2			entre entre de la companya de la companya de la companya de la companya de la companya de la companya de la co	. ₩2 🔲 Y	es [	No	Doesn't Apply
Required Inter	vention to Prevent Perma	anent Impairmen	t/Damage (D	evices)	T	mosis or Reason ( o Stop smoki		ion)	8 Event			After
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C. PRODUCT A\ Product Available for	VAILABILITY Evaluation? (De not ser	nd product to CC	A)		F 11 1	Professional? 3		Man 211.	i	-	Reporte	
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Yes No	Returned to Ma	nutacturer on:	(mm/c	id/ww		do NOT want your manufacturer, pla			า ไ	and the same of	ser Facil	My Monocler



#### B5. Describe event or problem continued

to my health -based on advertisements-, I constantly smoked - about 4-5 cartridges per day. planned on 4/9/12, I had the surgery; however additional stents were not placed because my surgeon determined that the affected arteries were not significantly blocked. I continued with smoking the e-cigarette including the night of the surgery. Immediately after the medical procedure I experienced a severe rash on my inner thigh of both legs and severe joint paint. Due to the timing of the surgery, I attributed these new symptoms to after-affects. Over the next couple of months, I continued to smoke the e-cigarette decreasing my intake from 16 mg, to 11 mg, and finally to 6mg while continuing the amount of cartridges of 4-5 per day. -I typically purchased these cartridges directly from www.premiumecigarette.com/.- During this time, my joint pain increased to the point of debilitation. The pain was excruciating and I could barely walk. It was so bad each day I that I thought it could not get any worse, yet somehow it did. My family doctor referred me to an orthopedic doctor and prescribed me ibuprofen - which provided some relief, but not nearly enough. Tests were ordered. -Thankfully, my test results for arthritis and cancer were negative. - At about this time, I found information over the internet to suggest that other people using the e-cigarette had experienced similar symptoms of joint pain. I immediately stopped smoking the e-cigarette and started to feel somewhat better. Basically, the escalating aspect ceased - in other words, it never got any worse. However, still the pain has been lingering. Even before reading the 2009 FDA press release -just read that today in search of somewhere to report this information-, I figured I was suffering the effects of chemical poisoning. The orthopedic specialist advised if my pain was based on toxicity, it would take approximately 3 months for expulsion. When I called my family doctor to determine if there is a way to hasten removal of the toxins in my system, he recommended purchasing a liver detoxification kit which I started last week. Hopefully, it will work. Just this past weekend I developed a rash on my arms similar to the one that had been on my inner thighs - do I dare hope that this is a sign that the toxins are departing? If there is an antidote to the type of poisoning that the e-cigarettes inflict on the body that the FDA is aware of, I welcome that you contact me with the information so it can be passed onto my medical personnel.

 U.S. Department of Health and Human Services

# MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Outcomes Attributed to Adverse Event

Hospitalization - initial or prolonged

5 Describe Event, Problem or Product Use Error

Patient Identifier | 2. Age at Time of Event, or

Date of Birth:

(mm/dd/yyyy)

chest. Finally, on June 17th, I

6. Relevant Tests/Laboratory Data, Including Dates

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

A. PATIENT INFORMATION

Unspecified

In contidence

✓ Adverse Event

(Check all that apply)

✓ Life-threatening

Date of Event (mm/dd/yyyy)

06/17/2012

emergency room.

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

Internet Submission - Page 1

More

Nore

More

(mm/dd/yyyy)

4. Weight

3 Sex

Product Problem (e.g., defects/malfunctions)

Product Use Error Problem with Different Manufacturer of Same Medicine

Required Intervention to Prevent Permanent Impairment/Damage (Devices)

After using an e-cigarette from the brand V2 Cigs, an recent incident sent me to the

e-cigarettes for a while, it is the first time something like this happened. I

Finally, on June 17th, I started vomiting violently for several hours and I decided to go to the emergency room because I felt so unwell I started getting concerned. While the doctors did not initially find anything life-threatening at the time, everything seemed to indicate either food poisoning

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

recently decided to try the V2 Cigs because of their popularity. However, upon starting to use the product, I notice that the nicotine cartridges appeared to be overheating. I switched with other cartridges of from the same V2 brand but each time, they overheated very quickly after just a few puffs. After a couple of days of using the brand, I started feeling unwell, nauseated and rashes appeared on my

Female

Male

Disability or Permanent Damage

∠ Congenital Anomaly/Birth Defect

4. Date of this Report (mm/dd/yyyy)

07/07/2012

While I have been using

√ Other Serious (Important Medical Events)

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

EDALISE ONLY

D. SUSPECT PR		
	nulscturer (from product label) tronic Medium	V2 Cigs
*1Cigarette	energia printing and a successive contraction of th	AND IN SOCIAL - 18-AND PROPERTY SOSSIES SOCIAL SOCI
2. Dose or Amount	Frequency	Roule
#1	T T T T T T T T T T T T T T T T T T T	****
		Buccal
#2		
3. Dates of Use(If unkn	own, give duration) from/to (or	5. Event Abated After Use
besi estimate)	06/17/2012	Stopped or Dose Reduced?
#1 06/10/2012	06/17/2012	#1 Yes No Does
***************************************		#2 Yes No Doe
4. Diagnosis or Reasor	1 for Use (Indication)	8. Event Reappeared After
	ensergefrene i stronen gan jappaga sa sa galam aya sa sa sa sa	Reintroduction?
#2		#1 Yes No W Appl
6. Lot #	7. Expiration Date	#2 Yes No Does
#1	*1	9. NDC # or Unique ID
#2	#2	
E. SUSPECT MED	DICAL DEVICE	
. Brand Name V2 Cigs		
2. Common Device Nan	rinner-manner-untervier-sensimen-unsprechensen in in in in in in in in in in in in in	
Electronic Cig		
<ol> <li>Manufacturer Name,</li> <li>V2 Cigs</li> </ol>	City and State	
. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (m)	Health Profession
	-aprilation Opto into	Lay User/Patient
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Serial #	Other #	Cither Cither
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Yes No

C. PRODUCT AVAILABILITY

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



#### B5. Describe event or problem continued

started vomiting violently for several hours and I decided to go to the emergency room because I felt so unwell I started getting concerned. While the doctors did not initially find anything life-threatening at the time, everything seemed to indicate either food poisoning or an It wasn't until they received the results of the blood work that they were able to make a final diagnosis. They concluded, based on the test results that I my body was reacting to the absorption of a rather significant quantity of nicotine. It was assume that the cartridges were probably leaking some of their liquid substance which I appeared to have ingested unknowingly. More puzzling, doctors also discovered traces of diethylene glycol in my blood. While they asked me if I had been in contact with any household chemicals or other products, they could not exactly conclude as to how I had been contaminated by that substance. They explained that I was likely the reason for my vomiting and that additional test were needed to see if any organs such as my liver or kidneys had been damaged. However, doctors believe that everything seems to point towards the use of the electronic cigarette. decided to sue the company based on the advice of the doctors who believe the product may be a health risk to others. While I am still waiting on the results of other tests conducted after the incident, the cost of my medical bills has escalated and the use of the product may have seriously compromised my health. I am providing you with this information in the hope that you conduct an investigation on your end so other customers do not find themselves in the same situation as me.

Mail to: MEDWATCH or FAX to: 5600 Fishers Lane 1-800-FDA-0178 Rockville, MD 20852-9787



## B6. Relevant tests/laboratory data, including dates continued

or an allergy. It wasn't until they received the results of the blood work that they were able to make a final diagnosis. They concluded, based on the test results that I my body was reacting to the absorption of a rather significant quantity of nicotine. It was assume that the cartridges were probably leaking some of their liquid substance which I appeared to have ingested unknowingly. More puzzling, doctors also discovered traces of diethylene glycol in my blood. While they asked me if I had been in contact with any household chemicals or other products, they could not exactly conclude as to how I had been contaminated by that substance. They explained that It was likely the reason for my vomiting and that additional test were needed to see if any organs such as my liver or kidneys had been damaged. However, doctors believe that everything seems to point towards the use of the electronic cigarette.

Mail to: MEDWATCH

or FAX to: 1-800-FDA-0178

5600 Fishers Lane Rockville, MD 20852-9787

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

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# MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1

FI	A USE ONLY	
Friage unit sequence #		
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Death							Ir e	Ababad After Han
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State of Event Interest and Degram of Product the Event   Product of Event   Product	[ ] Death	(mm/dd/yyyy)	Disability or Permanen	t Damage	#1 01/11/2012	07/10/	2012 #1 1	
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Second Name   Second Name	Hospitalization	n - initial or prolonged	Other Senous (Imports	ant Medical Events)	*?		*2 L \	
3. Date of Event (minds/pyyy) 07/13/2012 07/13/2012 2	Required Inter	vention to Prevent Permane	ent Impairment/Damage (C	evices)				
or/13/2012  i was using "premium" electronic cigarettes, and began finding when i couged up phlem it contained blood, these were 15mg nicotine, this had happend before but i did not associate it with e-cigarette use but i found when i stopped using them the blood disappeared from my phlem i think there is a direct correlation between users , furter i feel fda should investigate and advise the public if these e-ciga are safe or not    Summodive Manue.	3. Date of Event /mn	n/dd/yyyy) 4	Date of this Report (me	rr/ad/yyyyy)	*1 smoking		and the second second	CO Consess
i was using "premium" electronic cigarettes, and began finding when i couged up phlem it contained blood, these were ling nicotine, this had happend before but i did not associate it with e-cigarette use but i found when i stopped using them the blood disappeared from my phlem i think there is a direct correlation between users, furter i feel fda should investigate and advise the public if these e-ciga are safe or not    More			07/13/2012		#2		#1 [_] )	
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### B7. Other relevant history, including preexisting medical conditions continued

blood i would note i am not currently smoking

Mail to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787

1-800-FDA-0178

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FDA Internet Submission	an an	QR SEQUENCE TO	67001
Pallers identifier 2. Age at Time of Event, or 3. Sum. 4. Weight 166) (6) Fernale (7) Male or 160 b.	6 S PECT P 1. Hema Strength, M R-Cigaratte of	lanufacturer (Ippg groduct ta)	M Heelth E-Cigare
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Death: Disability or Permanenti Damage	91 07/15/2010	07/15/201	Stopped or Deep Reduced?
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Parquired Intervention to Prevent Permanent (impairment/Damage (Devices)  Date of Event (imm/ds/yyyy)  4. Date of this Report (imm/ds/yyyy)	ot other		8. Event fleeppeared After Reintreduction?
07/20/2010 07/20/2010 Describe Event, Problem of Product Use Error	#2 6. Los é	7. Expiration Culo	82 Yes No Doo
Ster using a e-cig, felt very sick and lizzy then started sweating badly. felt the	E1 BODS	87	9. NDC # or Unique ID
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	2. Curamon Device	Name	
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PAGE 02/07

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als of adverse events and product problems

Internet Submission - Page 2

85 Describe exect or problem continued

when inheled, induces these symptoms. Propylene glycol is NOT SAFE, and should not be allowed for human consumption, RSPECIALLY not for inhalation use. Please investigate propylene glycol and do something about these companies selling this dangerous product to Americans.

DSS

SEP - 2 2009

Mail to: MEDWATCH or FAX to: \$500 Flahers Lane 1.500-FDA-0178

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

KH I COER

Form Approved: CMM No. 0010-0051, Expires: 10/51/06 See CMB distances on reverse.

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The FDA Safety information and Adverse Event Reporting Program	Internet	Substantes	- Forth 1	DORS	mdance i	VE	41	שכ	
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3. Date of Event (mm/dd/yyyr)	4. Date of this Report (conditily)		87	en veneti	1000		0. Woutst 1 Flaketre		
84/03/2010	09/25/2010		42				#1   Y	<b>₩</b> 🔲	io Domin
5. Describe Event, Problem or Product Use			S. Lat #	7.	Papiellion D		#E   Y	<b>-</b> D	to Degar
I am writing with a co electronic Cigarettes.	Acers about MJoy		<b>81</b>	<u>*</u>			S. NOC #	Or Library	
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☐ Yhe ☑ No to NOT want your identity disabound nurselecture, place on "X" in this bear

FORM FDA 3500 (B/G5) Bubralenten of a report does not consti

☑ Yes ☐ No ☐ Returned to Manufacturer on

product caused or contributed to the years.







Describe event or problem continued

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ree VULUNIARY reporting by health professionals of adverse events and product problems Internet Submission - Page 2

take to control my heart rate, which was never an issue before. And I have never been sick or ill and felt just fine; until suddenly taken ill after use of Njoy. The medical staff said that inhaling water vapors is what rapidly caused my lungs to fill with fluids and thus threw The medical staff said we into Pneumonia and then congestive heart failure. Since that time I have not been the same person. I am always short of breath. I would be willing to speak with a PDA representative regarding this issue. I know that the FDA is attempting to regulate the industry and it should. had I knew the dangers I would have never purchased the product. Sincerely, (b) (6)

SEP 1 6 2010

MAR to: MEDWATCH or FAX to: 1-866-FDA-0178

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

MED WATCH

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Adverse Event represent regress.	: 14	4I)Kľ	1	·	
A PATIENT INFORMATION		2. or Amount	Proquent	y Route	
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R ADVERSE EVENT TROLLET PROBLEM OR EKKON		3. Detra of Use /// wakno	um alva duration) (	tomas 15 Byes	I Abated After Upo
Chack will that apply:		3. Dates of Use (If White (or hast autimals)		Stoppe	d of Does Reduced?
1. Advorse Event Product Problem (e.g., defects/meth/nectors)	- 11	#1 5/23-5/26		\$1 ₽	Yes No Desent
Product Use Error Problem with Different Manufacturer of Sema M	decicino	<b>2</b> 2			
2. Outcomes Attributed to Adverse Event		4. Diagnosis of Resson	tor Use (Indication		Yes No Doesn's
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Required Information to Prevent Permanent Impairment/Damaga (Davice		<b>#1</b>	#1	1	For Unique IO
3. Date of Event (mm/sd/yyy) 4. Case of this Report (ms/sd/yyy)		<b>e</b> S	- C		- en montage 18
5/25/2010 5/30/2010	<i>""</i>	E SUSPECTMED	E AL DEVICE		
5. Describe livent, Problem or Product Use Error		1. Brend Name	action to the state of the stat		
Several days after receiving and beginning to use	the	Blu Cigs			
Blu Cigs e-cigarette, I developed a persistent cou					
in addition to aches and sinus congestion (5/25).		2. Common Device Nam	e		
the morning of 5/29 my condition became much more severe, with symptoms including difficulty breach!		E-Ciçarette			
shortness of breath, chest pain, severe cough, joi	ing/	3. Manufacturer Name, (	the age! State	····	
pain, sinus congestion, sore throat and laryogitis	.	Blu Ciga, Unkno		igs.com)	
upon seeing a doctor, I was disgnosed with preumon	nia.				
The doctor prescribed me Levaquin and today (5/30)	א אות ו	4. Magail 8	Lot		
condition is significantly though not completely improved.	11	Starter Kit	Coto		6. Operator of Device
¥	- 11				Health Professional
	1[	Catalog #	Expiration i	ate (mindistry)	Lay User/Patient
	i I				
8. Retevant Testal aboratory Dale, including Dales		Serial #	Cither		Coher:
Chest X-ray (5/29/1010), Positive for Pneumonis	- 11	<b>74</b> (1) 4	Carps &		
<u>a</u>	- 11				
<b>=</b>	11	6. If Implanted, Give Das	(mmkldryyyy)	7. If Explanded,	Give Date (mm/dd/yyyy)
	l H	s is this I bingle-us D		244244	
		Y= F No	naver. nier mint Hel	Processed sive R	Eused on a Payent?
	11		or Name and Addra	no of Rebrusers	·
7 Other Balances Minter, Industry Street	السوسي				-
7. Deter Relevant Mistory, including Precising Medical Conditions of Allerta Conditions	VH				
Light smoker (C) pack a week)	▼ 44	E OTHER (CONC.)	MITAND HE	DICAL DEVOE	HC FC
1132	2040	Product cames and the			
JUN 01	ZUN		-his federical	· vernilend Of SAR	T TU
JUN 01 2010 MEDWATO					
JUN 0 1 2000 MEDWATC	in w	TI I			
-44ED4A/IO	" ' <b>Y</b>	G REPORTER (5-	· contributed	V 10 2150	N. 11
C PRODUCT AVAILABILITY		1, Slage and Arthur	Total Science Transaction (Const., pulmones, per		
Product Aveilable for Svaltandon? (De not send product to FDA)		Nam	(b) (6)		
	- []	Addr			
Yes No Returned to Manufacturer on:		1504, 115,463, 15,174 <b>4</b> 35, 525,57	2-15-14-15-15-15-15-15-15-15-15-15-15-15-15-15-		
D SUSPECT PRODUCTS:		cay: (b) (6)		State: NI Z	19: <i>0</i> 63
1. Heme, Greength, Menufacturar (from product lebel)		Phone 4	T	E-med	
Manac Starter Kit	111	(b) (6)	-	(b) (6)	
Strength: Light Manufacturer: Blu Cigs					The second secon
** Neno:		Mealth Professional?			. Also Reported to:
Sirengh:	11		Non-Healthcare		Manufacturer
Manufacturer:	- 11'	<ol> <li>If you do NOT want you</li> <li>In the manufactures, pie</li> </ol>			User Facility
FORM FDA 3500 (1/09) Submission of a report does not constitue		den Der Bedeel andere			Oletriboter/importer

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6735364-7-66-61 Adverse Event Reporting Program	ARY reporting of south of the second of the control
1. Puttern Montible: 2. Age at Time of Evert, or (b) (6)   Common (b) (6) (b) (6)   Familie (b) (c) (d) (d) (d) (d) (d) (d) (d) (d) (d) (d	1. Name, Strongth, Manufacturer (Appropriate labor)  o-cigarotta  ff  ff  ff  ff  ff  ff
Chack of that apply:  1. Adverse State:    Product Problem (n.g., defective of these States)   Product Use Street   Problem of the Different Membership States Stat	2. Date of Amount Programby Reside
Classit of their apply)	2. Deset of the (if unbrown, pive dutation) from/s (or best astimate)  2. Event Abstract After Use Stepped or Dece Reduced?  21
2. Demod Event (ministry) 05/18/2010 2. Demod Event (ministry) 05/18/2010 2. Demod Event (ministry) 05/18/2010 2. Demod Event (ministry) 05/18/2010 2. Demod Event (ministry) 05/18/2010 2. Demod Event (ministry) 05/18/2010	80   RefranceStation   Refra
essoke.net was advertised as "not having ANY carcinogens" and "all cartridges from raw DR materials" I visited the head location and saw materials being shipped in from China for use in the product and the s-cigaratte had checmical taste to it and malfuunctioned. This can be a serious health threat to the people seeking benefits from this product. FDA needs to investigate ASAP	
RECEIVED	A Blackel F Lot 6 5. Operator of Device  Graphs 9 Bughindan Date (mm/c/d/yyyy)  Lay User/Parlant  Backel 9 Other 9 Other
MAY 2 @ 2010	8. If Implimited, Give Date (ministryyyy) 7. If Explainted, Give Date (ministryyyyy)
MEDWATCH CTU  MEDWATCH CTU  MORE  Description Technology Date, Including Description	B. It this a Single-case Davies that was Represented and Researd on a Patient?  Was 1 No. 10 No. 4, Enter Harm and Address of Reprocessor
2 200 pp. 200 D 6	
7. Other Network History, Including Promising Medical Goodhory (e.g., eterpies, race, preprincy, smoking and addisoruse, eventurey problems, etc.)	(b) (6)
MAY 20 2010  Representations for Evaluations (Do not send product to FDA)  When I No Representations (Manufacturer on: (ministrator))	(b) (6)  R. Heelth Prefestional? S. Gotsuperfor  Van Pho Conservance/More-Book th  Manufactures  We have de NOT worst year identity disclosed to the manufacturer, plans on "K" in this tree.

FORM FOA 3600 (8/05) Submission of a report does not constitute an admission that medical personnel or the preduct assessed or contributed to the event.

51 ) Compliance

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50, 2021 05,01	<b>∞</b> • ,				
Individual Safety Report	vents, pro	RY reporting of duct problems and use errors	Trings unt 4/		0291, Empires; 10/21/06 IS statement on reverte.
560605-4-06-61		- Page 1 CDTS	R		<i>D</i>
Adverse Event Reporting Program  A DATE PARTIE DE DE DE LESS.		D LUSPECT PROD	bChái		
1. Peters Identifier 2. Age at Time of Event, or Date of Brits. (b) (6)	2. See 4. Weight 130 %	1. Marus, Grength, Marus Innovative Smol el	alarer (ligh) product labe		histication ds innocetive
6 ACVERSE SYSNE PRODUCT PROS		12			
Check all that apply:		2. Dose or Amount	Programo	<del>'</del>	Route
1. Adverte Event Product Problem (c.g.,					- P°
2. Outcomes Attributed to Adverse Event	The state of the s	92			
(Check all that apply)		5. Detect of Lieu (# unknown best ostmete)	n, gave duneston) framéto (o	7 5. Event All Stopped	of Dose Reduced?
(mar/dis/yyyy)	billey or Permanent Damage	64 03/17/2010	93/17/2010	A1 Z You	No Doesn't
	genital Anomaly/Birth Defect or Serious (Important Medical Events)	2		#2 □ VB#	No Doesn's
Hospitalization - initial or prelonged Office Resource Intervention to Prevent Portranent (1991)		4. Diagnosis or Assess to	f Use (Indication)		APP-1
	of this Papers (minidalyyyy)	51 51			mpreared Affer Mistigan?  Decemin
	04/09/2010	W2		61 🗹 Yea	Apply Apply
5. Damorika Evard, Problem 57 Product Use Error		4. Lot 6	7. Expiration Date	42 T Yes	No Docum
I bought a a item from Tune	ovetive smoking to	<u>m</u>	#1	A MDC + o	Unique ID
stop smoking and paid 220.	it was fda	12	段		
approved. I got very ill w	ithing a half hour	E. SURFECT MED:	CAL DEVICE		
of returning home. I went I were I boutht and the mana	back to the cart	Innovative Amol			<del></del>
my money. But his computer	would not let	2. Common Bovice Name			
him. He agreed that because	e I became ill I	A Manufacturer Name, C			
would want to return the was told that I would have	nused product. I	E Light			
to the home company, which	I did. I bave	4. Model F	Lot #		5. Operator of Davice
never heard from them. I for ten years I have a for	have been disabled	Carolog /	Expiration Out	(ווווווווווווווווווווווווווווווווווווו	Lay User/Patient
thought that this would ma smoking. I am on a fixed i	ybe belp me quit 🛶	Gorlal E	Other A		Z Oner.
aford	Market A. I.	6. If implement, Give Dak	(marketing) 7. W	Emplement, Glw	Daring (menyladdyyyyy)
		6. to thin a Single-use Or	wise that were Reprocess	and And Powerd	en a Patient?
		9. W Yes to Nam No. B. E	nter Name and Address	of Reprocusive!	
	26.6	£170 Orand Av.	Gurnes, X1. 6	0011 - EB	is address is
8. Relevant Team/Laboratory Data, Including Dates		were I bought	It as other add	ress given	
ESRECEIV	ED				
LONE CEIV	<b>E</b> D				
APR 13 2010 APR 13 201	in .		CHATCH LEASE OF		¥3
VDK TO THE MEK TO SAI	¥	*			
MEDWATCH	I CTU				
	[J. 43.4]				More
<ol> <li>Other Relevant History, including Pressisting Series, preparate, smaking and stands use, free field</li> </ol>	ney problems, etc.)		co contra mant,	war and and	racht
1		1. Name and Address (b)			
		(b) (6)		Bernedout view in the	
		(b) (6)			f. Hw.
Į.	<b>1</b>	Phon (6) (6)			
C FRODUCT AJAJLAD LITY		2 Health Professional?	1	1	. Also Reported to:
Product Available for Evaluation? (Do not send pro-	Nat to FDA)	☐ Yes ☑ No	MITEO		User Facility
Van No Activityed to Merryllada	Uner or:(mm/dd/serv)	to the menutadum,	der Monthly displaced pises on "X" in this box:	Ø	Z Diskinguranimpone

FORM FDA 3500 (A/85) Submission of a report does not constitute an admission that medical personnel or the product essueed or contributed to the event.

18003320178

414776

For VOLUNTARY reporting by health professionals of adverse events and product problems Internet Submission - Page 2

#### B5. Describe event or problem continued

to but a product that makes me ill. I do not know if I had a interaction with the meds that I take. The manager told me that I should not and that the product was safe and approved by the fds. There website also states that this product is approved by the fds. I would not of bought it if I had known that it wasn't. Thank You for your time.

ess APR 13 2010

Mell to: MEDWATCH

or FAX to: 1-800-FDA-0178

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

18003320178

MED WATCH CDER

U.S. De.



Form Approved: OMS No. 0910-0281, Expires: 10/31/08. See OMS eletement on reverse.

The FDA Safety Information and

Y reporting of act problems and product use errors Internet Submission - Page 1 - 000

Trage unit	410252	
iches		

Adverse Event Reporting Program	DOG	
A FAULTI INFORMATION	D SUSPECT PRODUCTIES	
1. Pertent identifier (b) 2. Age at Time of Event, or Dute of Strin:  Dute of Strin:  Percelo  Male  Of te	1. Name, Strength, Westellecturer (Figurated above 814 E-Cigarrete 1)	Blu
B ADVENSE F. FAT PRODUCT PROBLETION ENHAGE	62	
Check of that apply:	2. Dose or Amount Frequency	Route
Adverse Gverk Product Problem (r.g., defects/methinicitions)     Product Use Error Problem with Officent Manufacturer of Same Manufacture	12	
2. Outcomes Ameliated to Adverse Revent (Check all Plat agent)	2. Desire of Use (if Unknown, give dure lon) from to (or	5. Event Abeled After Use
Country   Diseability or Permanent Denistre	Coast distribute)	Stopped or Dose Reduced?
Life-fringtoning	92	40 Type Tue Docum
Hospitalization - Initial or protonged (Other Serious (Important Medical Events)  Required intervention to Provent Persuanent Impolarment/Damage (Devicus)	4. Diagnosis or Remon for Use (Indication)	8. Event Russparred After
1. Date of Event (ministryyy) 4. Date of this Report (ministryyy)	•1	Reintroduction?
03/03/2010 03/03/2010	et;	FI Yes No Deservi
S. Describe Event, Problem or Product Use Error	8. Lot# 7, Raphytien Date	#2 Tes No Dosen's
After 3 days of using Blu brand electronic	, saknown	8. NDC # or Unique ID
cigarettes i experienced what i may only	<b>12</b>	
guess to be my first migrane in my life. above my left eye a pounding pain and an	E EURPECT MEDICAL DEVICE	
extreme sensitivity to light and sound.	1. Brund Name	
offects went away when i stopped smoking the ecigarrate but came right back when i tried	2. Common Device Name	VIV
to smoke it again later. since stopping the product i have experienced none of these affects. why is something not even tested	5) Manufecturer Name, City and State	
allowed to be sold in the usa?	4. Model 6 Let 6	5. Operator of Device
	Catalog # Expiration Onto	Monthson
	Other month party	Lay User/Patiens
	Serial # Other #	Other:
	8. Il Implemed, Give Date (mm/dd/yyyy) 7. If E	Explanded, Give Date (mendalyyyy)
1		of and Daymed as a Button
	B. In this a Single-use Device that was Reprocessed  Yes No	
	9. U Yes to Item No. 8, Enter Murrey and Address 4	
S. Rebryant Touts/Laboratory Data, Instuding Dates	M.	AR 8 4 2010
	A STrept .	110/2000
	MEDI	WATCH CTU
	Froguet names and theory define (suchdo heath	
	_	
		DSS
Mara	MAD	-4 2010 More
Conver Releasest History, Including Presidenting Medical Conditions (e.g., storgiss, race, pregnancy, smaking and alcohol use. Inventidinal problems, etc.)	C. PEPORTED Seasontinentally s	
THE STATE OF THE S	1. Nume and Address	
	(6) (6)	
	Phone 4 Per	ell .
Bord	2. Health Probasional?   3. Competion	4. Also Asperted to:
FROUTCE AN AIL // BILL TY  Freshest Available for Evaluation? (Do not send product to FDA)	Yes No	Marsufecturer
7 vet  No  Returned to Manufacturer on:	5. If you do NOT went your identity disclosed	UserFacility
TAME THE PROPERTY OF THE PROPE	no sine memoriacturer, place on "X" in this bes:	District de la Constant de la Consta

N. V. Barrana at Ata Ata Ata Ata Ata Ata Ata Ata Ata	MINIS
U.S. Department of Meadle and Human Services  Individual Sefety Report	Fan Brown CMB No. 0010-0201, Expires: 10/31/06
	.Y reporting of Serverse.
	uce problems and
	Trings link 388266
Agve: 6303063-5-68-81	- Page 1/,
A. PATERTINE GREATION	16-
	D SUSPECT PRODUCTOS
Date of Birth:	1. Name, Boongth, Manusboturer (from product label)
B AS /ERSL EVENT PROBLEM OF BALLS OF BARANK	12
Check of that sould:	2. Does of A
	2. Dots at August / Frequency Rollin
1. Adverse Event Product Problem (a.g., detections/proteins)	"
Product Use Error Problem with Different Manufacturer of Same Medicine	12
2. Outcomes Attributed to Adverse Event (Check all shal apper)	1 []
	3. Detect of Use(if upbrown, give curstion) Ironite for S. Event Abelief After Use
(makkim)	Rapped or Done Reduced?
☐ Congenited Anomaly/Birth Detects	FI Yee No Count
Hospitalization - Initial or prolonged Other Serious (Important Medical Everal)	#2 You No Down't
Required intervenden to Prevent Permanent Impairment/Demage (Devises)	4. Diagnosts of Researt for Use (Indication)
2. Date of Event (enn/dd/yyyy) 4. Date of this Report (mm/dd/yyy)	6. Event Responsed After Reintreduction?
08/07/2009 08/07/2009	41 Yes No Document
5. Describe Event, Problem of Product Use Error	- A0(D)
•	6. Let 8 7. Repiretion Onle 12 Yes No Document
Yes, I bought an electronic cigarette and	8. NDC F er Uneque ID
want to report a very had adverse effect. Your ban of them. As a two pack a day	n. 2
smoker for 25 years, I thought there was no	C. COSPECT MEDICAL DEVICE
hope. I tried all the MTRs that the market	1. Briang Manus
had to offer, even non conventional ones	Amoking Everywhere Blectronic Cigaratte
·hypnosis, voodo doctor blok magic, atc-,	2. Common Device Name Petrophal Vennorizar
yet I could not pull myself away from the	A Menufacturar Name, City and State
deadly digarettes. I then tried	
electronic digarettes months ago, My quality	
of life has dramatically increased since I	4. Model # 5. Operago: of Devise
started using them. So far - I can breath again - I have more energy - I no longer	DEXIO) B/a Health Professioned
have chest pains waking in the morning - I	Catalog # Expiration Dala (mundal)/////
no longer cough up a lung - My primary	Serial 6 Owner 9 Other:
physician, who	m/•
	6. If Implanted, Give Date (men/407yyy) 7. If Explanted, Give Date (min/40/yyyy)
,	
	S. In this A Single-tree Device that washington by Bear than a Page 17
	9. If Yes I No Ben ba. S. Feder
lore	N. H. Aster to territ set of Exists services demandrates (A. Marines demandrates
S. Relevant Yesta Laboratory Data, including Dates	AUG 1 0 2009
Vanta and and and and and and	WOO I O 5003
Look up your own test results of the alectronic digarette and compare it to a	
real one.	MEDWATCH CTU
•	F. OTHER ICONCORNTANT, METRCAL PICE DUTS
	Product names and thompy dates (exclude hashman)
	AUC + C cane
	AUG 10 2009
Nore	
7. Other Relevant History, including Pressisting Medical Conditions (e.p., alorgies, race, programoy, amolang and elabolic use, investiging propiets, stc.)	Hora
	G. REPORTER (See confide status section on task)
I smoked over 2 packs a day, Now down to 0 packs.	1. Nonte and Address
Again.	(b) (
	Phone (   E-mail
(371)	(b) (6)
C PRODUCT ANAMAD LITY	2. Heart Providerant / J. Cookpanion et . Auto No parent 40:
Product Available for Evaluation? (Do not send product to FDA)	☐ Yes ☑ No Administrator ☐ Manufedum
Yes No Relutted to Manufacturer so:	5. If you do NOT went your identity displaced User Facility
(mm/sa/yyy)	to the menufacturer, place on "X" in this box:
FORM FDA 3500 (8/05) Submission of a report does not constitute an ad-	Intenion that medical demonster or the product squart or many beaut to the second

PAGE 86/37

MED WATCH



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ls of adverse events and product problems incurred submission - Page 2

B5 Describe event or problem continued

has been monitoring me for an unrelated health issue, found my lung CAT scans clearer and my blood test results much better then when I started. Now the REAL adverse effects, which are life threatening to me, 1s your ban of them. NOT due to public health, but because of the \$2.314 BILLION lost in taxes, Big Pharma, and Big Tobacco interests. Your agency is going to be DIRECTLY RESPONSIBLE, for the next round of deaths due to tobacco use. Not only because you decide to ban a safer alternative that your own report PROVES what the electronic digarette manufacturers claimed ALL ALONG, that they are far safer, but also because you now regulate real digarettes. So the alterior motive is clear. So, consider this "Adverse Event" the report to the FDA in behalf of the 400,000+ who will die this year alone due to tobacco use.

DSS AUG 10 2009

MAIL LO: MEDWATCH

VATCH or FAX to: Ishere Lahe 1-806-FDA-0178

5800 Fishers Lahe Rockville, MD 20862-9797

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

U.S. Occurrent of Months and Human Readon Individual Safety Report			OMB No. 0910-0201, Expired: 10/31/08
	ARY sporting of oduct problems and	0.1	See OMB statement on reverse.
	use errors	Triege unit 36	39335
A PATIENCE VS JANUA	Care		
1. Pollure Idontifler 2. Age at Time of Event, or 3. Sex 4. Weight	O SAUSZZE I STORA 1. Name, Swength, Manufac	/UNION Sharer (Sprin product leave)	tine Green Smoke, Inc.
(b) Description:   Permais   200 b	Green Buske	estridge Didd	tive Green Smoke, Inc.
B. ADVERSE EVENT PROBUCT PROPULER OR STODIC	62		
Check all that apply:  1. Z Advarde Event Product Problem (s.c. detectional confirmation)	2. Dose or Amount	Frequency	Route
Product Use Error Problem (e.g., detectional functional     Product Use Error Problem with Citiesus Manufacturer of Borbe Musicing			ро
2. Outcomes Attributed to Adverse Svent (Check all therappy)			
Death: Death Disability or Permanens Carrage	1. Delay of Use(/ unlerown, bout selfmale) One tim	<b>1</b>	5. Event Abulad After Use Biopped or Date Reduced?
Lite-threatuning Congential Anomaly/Minn Detect	81 07/18/2009	07/18/3009	P1 Yes   No   Doesn't
Meepfalitzalien - infiel or protenged Offinit Surisus (Amportant Medical Events)  Required Intervention to Prevent Permanent Impairment/Demage (Devices)	4. Disphosis or Resson tor	- (in firefrator)	#2 Yes No Dosen't
Date of Evant (mind(h))))     A. Date of this Report (mind(h))))	to cut beck on	regular	6. Event Responsed After Reintreduction?
07/18/2009 08/19/2009	#2		#1 Ves No Domin't
6. Describe Event, Problem or Product Use Error		. Expiration Date	72 Yes No Desert
Experienced a severe headache and neuses. She had to go to sleep for several hours		<u> </u>	9. NOC 4 or Unique 10
then felt better upon waking.	E SUSPLCT (ISDIC)	Z S. DEMCE	
	1. Sryad Natur Green Smoke		
	2. Chiamon Device Name		
	3. Manufecturer Home, City	and State	
	Green Smoke. Inc florida	manufacturer to	ohina/distributer in
	4. Model # green smoke #1	Late	5. Operator of Device
	Cassion 4	Expiration Data (m	revisityyyyy
	Serial 8	Other #	Other:
	6. If Implement, Olive Date (M		planted, Give Date (ministrations)
	A. to this a Single-use Device  Yes No	that was Represented	and Reused on a Patient?
Magna	D. If You to Room No. G. Enter	Name and Agaress of R	) p/Scenero/
3. Relevent Testafusbruitry Date, Including Dates			
Mone DECCUED DOC			
RECEIVED DSS			
AUG 2 0 2009 AUG 2 0 2009	<ul> <li>STREET CONCORD</li> </ul>		
	Product name and thoragy	dame (excinct ventue)	d event)
MEDIVATOH OTU			
			A PRO
7. Other Relevant History, including Presticting Multical Conditions (e.g., ellegies, race, pregnancy, smoothy and alcohol use, Providency presistant, etc.)	G REPORTER (See	epotidicatically sec	
Wothing other than smoking history of 20	1. Nume and Address		/AX
years. Never had this type of reaction to conventional digerattes			(b) (
İ	Divers A	Facel	
I	[ [""		(b) (
Nore	2 Martin Barbardan St To	Acres of the s	A Step Branches
C PRODUCT AVAILABILITY	2. Madiin Professionai? 5. (	Occupation	4. Alse Reported to:  Manufacturer
	1 1 L	Jamily (Bickree)	· · · · · · · · · · · · · · · · · · ·

			المالية . 10 كالمالية :		
And Videal Safe	ty Report	CARY reporting of		provest CMB No. () Sec	810-0291, Explore: 10/31/01 OMB statement on reverse
		noduct problems and		i e die t	
		l use errors	Triage unif	3866	581
6266763-3-66-61	A	.us - Paga 1	<del></del>		
A PARCTHER OF A LON		U JEPECTION		<u> </u>	
1. Perfort Identifier 2. Age at Thee of Ever		1. Hame, Strength, Shandar	durer from erad.	et Interii	
Date of Shift:	Formato 190	Smoking everywh	ere 'alfa a	icotine : per	mostod enerhapet
in confidence 41 Years	Z Man	100			<del></del>
Brook all that Apply:	Control of Hash	2. Dose or Amount	Proc	Juney	Amele
1. Z Adviras Event Probabl Prob	blum (s.g., dalocty/math/mytera)	st my 3 - 3 cats	Litgas da	ily	
Product Use Error D Problem with	Different Manufacturer of Server Magicine	12			
Concorned Attributed to Adverse Brest					
(Check all that apply)  Double:	Cleability or Permanens Democra	2. Delet of Ven If witness,	give qualitary has	We for 6. Eres	Ahoud After Use and or Dose Redgeed?
(material y y y y		p 07/17/2009	_ 07/25/		Yes   No   Done
Life-throughoring  monohistation - inties or evaluation	Corporitoi Anomaly/Birth Deliver  Other Serious (Important Medical Even)				Yau Data Docum
Required inservention to Prevent Pearty	·	4. Disampais or Sesson for	Use (Indication)		Apply
3. Date of Event (com/ddygyy)	4. Date of this Report (maniatives)	Alternative to	traditions	A. Ebreyo	Respected Alter reduction?
67/25/2009	07/29/2009	Q.			Yes Ato 7 Doesn'
Desarthe Event, Problem or Product Vice	Liver		7. Empiration De		Apply
	*moking everywhere's*				TO LADBY
	of both myself and my		-	9. NDC	8 er Unique IO
spouse, jointly experi		<b>6</b> 2	R		
feelings of disorients in our vision -depth ;		1. Brand Horse	14 6 6 6 7 7 5		
blurred vision - along		Anaking Everywhe	89		·····
occasional nauses, thi	is only occured after	2. Commen Device Harry Electronic Cines	attma		
continued use of the		3. Manufasturer Home, City			
electronic cigarettes, period of use to be re	-	Smoking Everywher Sunrise, PL 33351		5600 MM 10	Isd Ave. Stite A
weeks, after discontin		4. Model #	Late		5 Operator of Device
mentioned symptoms as	amed to decrease				Health Professions
	ace we resumed smoking	Çolming e	Expirate	י (ייניקלטט'איזמיי) שערט יי	Lay Usan Politica
of traditional tobacco	acommend the the	Sertei é	Other 6		Z 00=c
*s-vigarette" industr					purchaser/00
-		S. If Implanted, Sive Date (	(KEN/400)	7. If Explorated, C	itve Dam (mented/yyyr)
					ed en a Pallacit
		A. In this a Single-use Davi	the that were flags	Accessed the Contra	
		□ v= ☑ v=			
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04/02/5011 51:12 18003350148



VATCH

ionals of adverse events and product problems

65. Describe event or problem continued

much higher accountability for both product testing and quality control.

**D55**JUL 29 2009

Makso: MEDWATCH

or FAX to:

5900 Flehere Lane Rockville, MD 20852-9757

1-800-FDA-0178

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



# **VATCH**

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sionals of adverse events and product problems
Internet Submission - Page 4

B7. Other relevant history, including preexisting medical conditions continued

or so of use of the smoking sverwhere "e-cigarettes"

**DSS** JUL 29 **2009** 

MEDWATCH

orfax to: 1-800-FDA-0178

6860 Fishers Lane Rockville, MD 30662-8787

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

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wall and could barely s	tend. I was told	4. Madel 5	Lot			S. Operator	of Bavica
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MED\	NATCH CTU				•	~ ••	-
	More				JAN	282	2011
<ol> <li>Other Relevant History, Including Prescribile race, pregnancy, amoining and alcohol use, live</li> </ol>	ng Medical Conditions (e.g., allergies. Inhidrey problems, etc.)	G REPORTER (See	Secretary of the second	(1,			Wite
I have no previous conduse, I do smoke digaret pregnant, Im white -rac healthy other than migr	itions, no alcohol tes. Im not e- and generally	(b) (6)		THE WATER			40 C. Maria
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FORM FDA 3500 (8/05) Submireles	on of a report does not constitute an ad-						
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Individual Safety H

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regionals of adverse events and product problems Internet Submission - Page 2

#### B5 Describe event or problem continued

amount as the previous oil I had. By that afternoon, all my symptoms had returned. Once I stop, the symptoms go away in about a day or so. Back on the e-cigg, they come back within just a few hours. Same symptoms as above. Then I stopped using it and the symptoms slowly went away in about another day. I called the seller again and was told it must be all in my head because these e-ciggs are 100% natural and there is nothing that can hurt you. Im not sure if its micotine or some other chemical when you "smoke" it, but I was really really sick. My husband wanted to take me to the hospital, but I dont have insurance, so I didnt go. But, it was really bad. Very scary.

> DSS JAN 28 2011

O PRODUCT AVAILABILITY

POUR Available for Evaluation? (De not send product to FOA)

Y No. No. Returned to Manufacturer on:

to the manufacturer, sk FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product counsed or contributed to the eve

5. If you do NOT went your identity disclosed

Other Bealth

me en "X" in trie cons

(b) (6)

✓ Yes □ No.

More

Ushulacturar

User Fecility

Distributor/importe

Safety Report Individual

tions identifier 2. Age at Time of Event, or

(b) (6)

Required Intervention to Provent Permanent Impairment/Demage (Devices)

For 1 week I attempted to quite smoking using a device called an e-cigarette or electronic cigarette. The e-cig. that I used is made by Sinless Smoke. A few hours after using the product I notice that I was becoming irritable and moody. That night when I tried to sleep I noticed that I was not able to fall asleep I had strong

feelings of paranois and hellucinations. The symptoms grew worse and worse with my continued use. I thumbed through the user manual and discovered some interesting warnings. The device has an atomizer used to convert the liquid micotine along the air you are sucking through it to "harmless

I researched cigarettes and the Internet and found that each digarette contains 1.5mg of nicotine per cigarette and the owner's manual stated that each drop of "liquid nictotine or juice so the refer to it." contains 24mg of nicotine per drop and you drop 6 drops into the cartridge each time

 Other Relevent History, including Presenting Medical Conditions (e.g., sharpers, reco, pregnancy, emoting and attothol use, fiverhidney problems, etc.) I am a 2 pack a day cigarette smoker and

that is why I used the product.

Product Available for Evaluation? (Do not earld product to FOA)

C. PHODUCT AVAILABILITY

Adverse Event.

Product Une Error Problem (e.g., delecte/ingl/incline)

Product Une Error Problem with Different Nemadapturer of Bassa Negatine

Fearule

Disability or Permanent Demoge

Congenital Anomaly/Rinh Delosi (Important Medical Events)

4. Date of this Report (min/ddyyyy)

08/31/2009

**2** Maso

FROI JOT PROBLEM OF ERFOR

(b) (6)

Charact of that apply:

(Check of that suply, Destr:\_

Life-threatening

3. Date of Event (monthstyggy)

00/26/2009

AUVERSE EVEIR

Outcomes Aftributed to Adverse Event

Degradant to letter - Adizzational

5. Describe Event, Problem or Product Use Error

(arrettyryy)

water vapor" that you exhale.

S. Relevent Yeste/Laboratory Dels, Including Dates

SEP 03 2009

VOLUNTARY reporting of se events, product problems and product

Submission

Form Approved; OMB No. 0910-0291, Expires: 10/91/08

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- 2000 1 DQR	,	W-F-2
D RUSFELT POO	DUCTINA	
1. Name, Brength, Manu Staless Smoke	lasterer (Room product laber)	
41		
R		
2. Close or Amount	Frequency	Route
#1 24mg drops 6	9.12 ti	po a day
62		
3. Dame of Use (f unknow	iri, give duration) france (or	5. Evers Abeled After Use
Salt witing (0)	-	Glopped or Coss Reduced?
#1 08/18/2009	08/26/2009	Acoty
43		#2 Yes No Domen's
4. Diagnosis or Resson to to stop smoki	ing (vestament)	6. Event Reopposited Alter
		Reinvolution?
62	T Bunketten Data	- Apply
e. i.c. 1	7. Expiration Data	#2 Tee No Doesn't
<u> </u>	-   1	9. NDC # or Unique ID
62 COLUMN SERVICE	1001 051005	
E. PURPECI BLED	TORE DECK E	
Sipless Sucks		
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F. OTHER CONC	OMITANT MEDICAL	
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(b) (6)	(b) (	6) 4. Alse Reported to:
2. Health Professions!	7 3. Occupation Consumer/Mon-Rec	.
5. If you do NOT want	<u> </u>	Upper Facility
2. II yeu as RUI was	year reserve and be said bear	7 Distributor/bysorter

Yes No Peturned to Manufecturer on: 08/29/2009 to the menufecturer, place on "X" by this box: (mm/ddi/myy) Submission of a report does not constitute an admission that medical personnal or the product caused or contributed to the event. FORM FDA 3500 (8/05)

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91:12 1102/50/00

More

2010

Hors

you



85 Describe event or problem continued

The warning clearly states do not us if atomizer is not functioning properly due to rick of radiation poisoning. I am not an engineer or a scientist so I would not know if it was or was not working properly. My wife stated to me that my positive upbeat energy was non-existent while using the product. I even became depressed as a result of this product. I think the FDA should monitor this product and run their own tests before allowing this product to be sold on shelves.

SFP 03 2009

Mel to: MEDWATCH

or FAX to: 1-800-FDA-0178

5600 Piehers Lane Rockville, MD 25662-9767

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



66 Relevant tests laboratory data including dates continued

refill it.

DSS SEP 03 2009

Mali to: MEDWATCH

or FAX to: 1-800-FDA-9178

8600 Fighery Lane Rockville, MO 20052-2787

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

LIJIMI Individual Safaty Report CDER Form Approved: CNB No. 0810-0291, Expires: 10/51/06 Bee CNB esterment on revenue. OLUNTARY reporting of events, product problems and product use errors DOR uhmission - race 1 Adverse Event Reporting Progri MOITAMPORID MATTE 138 (b) (6) Dakang/Roge (b)(6)Mitotine eliquid ADVERSE EVERH Check all that apply: Dete or Amount 1 **ing/s**). delly Product Problem (e.g., defects/mathecolons) Inhal 🔲 Product Use Erfor 🔛 Problem with Different Manufacturer of Same Medicina Outcomes Attributed to Adverse Event (Check all their apply) Event Abased After Use tes at Use (if unknown, give duration) fromto (ar Death: Clinebilly or Permanant Damage (Particulary) at 07/02/2009 08/29/2010 e1 🗌 You 🗹 No 🔲 Doe Ule-Breatening Congential Anomaly/Sinti Delect Hospitalization - initial or protonged Other Seriose (Important Headical Events # □ Yw □ No □ Ω Required intervandon to Prevent Perm agrees or Resson for Use (Indication) Sicotine Withdrawal prent Impairment/Damage (De 6. Sweet Room 2. Date of Event (eventidyyyy) 4. Date of this Heport (mm/dd/yyyy) PT Ves No Door 09/05/2010 09/16/2010 5. Describe Event, Problem or Product Use Error 7 Familiation Date #2 Type No Desc en mone on bottle Patient quit amoking a 15pack/yr habit in 9. NDC # or Unique ID July of 2009 and started using a Joyetech 12 12 510 brand electronic cigarette and verious none exist flavors of 18mg/ml "eliquid" nicotine juice PEUR AL DUVICE at that time. 3 months later patient Joyeteem \$10 electronia cigarette reported significant loss of visual acuity Ahan Davis Hure in his right eye -which was already myopic elegizonie rigeratte 3. Mandesture Marie, Dily and State but corrected properly with Rx lenses- and a "haziness" around lighted objects. Patient Jovetoch, shanzen, China was diagnosed with the early stages of Posterior Subcapsular Catract in Oh and his A Marial # 5. Describer of Charles RX lens was changed to get him back to 20/25 510 oose emists Health Protessions vision in that eye in March of 2009. Over Catalog # Expiration Date (min/dd/yyy) Law Used Pasters the course of the next 6 months his vision Other in right eye rapidly deteriorated and on Serial d 9/9/10 he was B. If Implement, Give Date (min/dd/yyyy) 7. W Explanted, Give Date (remidd/yryy) 8. In this a Single-use Device it Yer No SEP 17 2010 P. F Yau to form No. S. Enter Name and Address of R Here SEP 17 2010 6. Relevent Trests/Leboratory Date: Impliging Dates OD refraction and exam by (b) which MEDWATCH CTU elucidated the PSC as L4 on 9/9/2010 . Previous exam by optometrist in March of 2009 initially disgnosed the PSC. OFHER CONCORPIANO MEDICAL a and therepy dates (explude beginned of electric Other Relevant History, including Prescisting Medical Congettons (e.g., allergies race, prepriancy, emoleng and elcohol use, the Medical proplems, etc.) C MERCHILA 150 1. Name and Address Patient is caucasian male; Smoking 15pk/year which ended in July 2009. NEDA or other drug (b)(6)usa. 50 A FILIBALIANA TOURCHY Pharmacist 2 Yes | No Marufacturer Propert Available for Evaluation? (Do not send product to FDA) Veer Facility 5. If you do NOT want your latedly disabound Yes Z No Returned to Manufecturer on: to the manufacturer, place on "X" in this hou: Distributor/Inte (mm/ss/pps/) FORM PDA 3500 (\$405) Submission of a report does not constitute on admission trial medical personnel or the product caused or contributed to the event

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rofessionals of adverse events and product problems Internet Submission - Page 2

B5. Describe event or problem continued

seen by opthamologist (b) (6) and diagnosed with L4 PS cataract and was deemed legally blind in his right eye. Patient will require Lens replacement surgery in that eye to correct this problem-which has been scheduled for 10/26/2010. The only factor that changed in patients life during the time frame of aggressive caparact development was the switch from smoking to the use of electronic cigarette product.

> DSS SEP 17 2010

Mall to: MEDWATCH

OFFAX 10: 1-800-FDA-0178

8600 Fighers Land Rockville, MD 20062-9787

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

oduct	use errors CDRH sequences 43839
1. Patient lampling 2. Apr 21 Years of Event of Date of Sirgh:  74 Fortigin or 55.5 to 122 to 122 to 125 to 122 to 125 to 122 to	MJoy e-cig daily smoke/inhale
Check all that apply:  1.  Adverse Event.	1. Deles of Lips (Frankrown, give develor) Foliable (or best celebrate)  81 11/2 to 11/6 throughout day  82  4. Diagnosto or Research for Lips (Indicative)  91 Smoking cossation  82  91 Peer No Doesn's Agely  82 Yes No Doesn's Agely  83  94 Peer No Doesn's Agely  95 Smoking cossation  96 Peerl Response After Relative Agely  97 Agely
Hospitalization - initial or protongest   Other Serious (Important Medical Everal Required Medical Everal Protonge (Devices)  3. Dark of Event (Immedifyyyy)  11/06/2010  4. Data of this Report (Immedifyyyy)  12/19/2010  5. Describe Event, Problem or Product thes Brow (b)(6)  age 74 discharged from hospital on 11/2 recovering from pneumonia. Home health nurse visited each day at home to administer antibiotic through PIC line. No problems noted during administration of meds, bp, temp, etc. Dpon discharged pulmonologist gave the OK to use electronic cigarette instead of spending 35 on expensive micotine patches. (b) smoked for 60 years! Got the NJoy electronic cigarette and used that everyday with an visible side effects. The night of 11/6/10, went to bed 9:30 pm, wife checked on him at 10pm and Ne was fine. Diffs went to bed at 11:30 and noticed he was	91 92 92 1. Brand Name MJoy electronic cigarette 2. Common Device Name E-cig
mumbling something. Turned on light and found (b) staring at calling saying "I'll be alright in a 0. Relevant Term/Laboratory Data, Including Dates  RECEIVED  DEC 3 0 2010	Catalog 8  Expiration Date (mm/GS/yyyy)  Lay Usel/Patient  Other:  Other:  0. If Implicated, Give Date (mm/GS/yyyy)  7. If Expirated, Give Date (mm/GS/yyyy)  8. In this a Stagle-see Davice that was Represented and Streams on a Poliphi?
7. Other Relevant History, including Projecting Medical Conditions (n.g., altergies, race, programsy, emoling and alcohol use, Averticinay problems, asc.)	Two Man R. Cor has an Address of Representation
Product Available for Evaluation? (Do not send product to FDA)  You No Returned to Menufacturer on:  (Miles 1977)  1. Name, Strength, Manufacturer (Non product label)  91 Name: Strengt:	(b) (6) USS  (b) (6) DEC 3 0 2010 (b) (b) (6)
Menufecturer:  92 Name: Strength:	2. Health Professional? 3. Occapation    Yes   No   Non-Healthcare Professional   Manufacturer

#### "NTARY reporting of and product problems

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age 3 of

minute" Wife and daughter asked him if he was in pain, etc. while the wife called 911. Once on the line with 911, his whole body started to tremble and shake and sound like he was swallowing his tongue. He was using an oxygen concentrator at night and wife made sure that stayed in his nostrils during the "seizure". 'His eyes remained open during the event. Once the paramedics arrived, "deizure" was over but they rushed him to the nearest ER, put on vantilator and his BP was so low they couldn't take blood samples, so had to give him meds to raise BP. ER staff said CAT scan showed no sign of stroke. Neurologist did spinal tap--results clear. EEG showed brain activity but "slow". MRI was clear. They decided that he must have aspirated something into his lungs while laying down. He was talking to use

prior to the trembling! He was ICU for 10+ days and once off the ventilator, he could not talk, eat or swallow. He knew who we were and a feeding tube inserted. After several days swallow test showed he could now eat soft foods and eventually began to talk and eat normal food. Memory was the problem. He had lost 20 years at times but we figured it was due to being in ICU for so long. At this time he is now in a skilled nursing facility/rehab, still having memory problems and may end up being in a nursing home long term because he is considered a sefety risk since he cannot walk with the aid of a walker yet. "His is a man who was totally ambulatory and active until 11/6: The only difference between being discharged and the "seizure" was the e-cig-had we known there were side effects, he wouldn't have

0.6. Relevant Testal abaratory Date, Including Dates (continued)

11/7 CAT scan, spinal tap, EEG, MRI

D.7. Other Relevant History, Indicating Pressisting Medical Conditions (e.g., alongino, roce, pregnancy, analong and attained use, repetitioned dynamics, etc.) (continued)

Heart attack 1987, another heart attack October 2010 due to pneumonia. Slight stroke 15 years ago only had weak left hand, no other problems. Smoked for 60 years. He is a white male, 74 years of age, retired due to heart condition, being treated for COPD, heart disease prior to 11/6. Smoked 1 pack of filtered digrattes per day.

F. Concombant Medical Products and Therepy Dates (Enclude treatment of event) (continued)

DSS

DEC 30 2010

	se events, pr	th I reporting of oduct problems and		THE GOLD	Unity Statument on reverse
BO ELIA Solohi intermetion and	product Substaate	use errors De	Triage unit	432d	63
A PATIENT INFOFMATION		D BUSPECT PR	100JCY(8)		<b>-</b>
Patient Identifier  2. Age at Time of Event, or  7. Specified  Date of Birth:  7. Fermio	4. Weight 160 to		Militarium (from produ	or label) IG. 13 mg	
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S ADVERSE EVENT, PRODUCT PROBLEM OR ERS Shock all that gook:	SOR	2 Dose or Amount	Free	eency	Route
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Product Use Error Problem with Different Manufacturer of Ovicomes Attributed to Adverse Event	Same Medicina	*2			
(Chock of that apply)		3. Dates of Use of units bast authority	nown, give duration) from		Albeing After Vee
Disability or Permanet   Life-throatsing   Congenital Anomaly/8	· 1	#1 10/07/2010	10/07/		ed or Door Reduced?
Hospitalization - Initial or prolonged   Other Serious (Import	i	#2			Apply  No Doesn't
Populind Intervention to Prevent Permanent Imperment/Darlage (C		4. Diagnosis of Reaso want to qui	n for Use (Indication) t spoking		Reappayed After
Date of Event (mm/dd/yyyy) 4. Date of this Report (m 10/09/2010	##### (### )	#2			eduction?
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used an electronic cigarette for th time. Took ten drage in a period of	e first	#1	<u>e1</u>		or Unique ID
an hour. As I was smoking it I stated feel high, dizzy, foggy, and just	rted to	E. SUSPECTIVE	DICAL MENICE		
disconnected mentally. The feeling		1. Brand Negre smokestik JET			
from it was not a good high, but kin creepy. I also started to feel tir		2. Common Device Na			
went to sleep, got up through out the and still felt disconnected. In the		3. Menufacturer Name	• •		
I felt a little better, but still no	ot right.	Sackastik Gree			
It wasn't until mid day where I fel self again. I am wondering if it w		4. Model #	Los #		Operator of Davice     Health Professional
P.G. in the e-cig. that made me fee: way.	l this	Cutalog #	Expresson	Date (mm/dd/yyyy)	Lay Used/Patient
-		Sorial 1	Other #		Other:
		5. If Implement, Give D	tin (mm/dd/yyyy)	7. Il Esplanted, Gh	e Date (meddd)yyyy)
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OCT 13 2010		TOQUET PARKET ENG S	erapy dates (exclude i	regionant of event)	
MEDWATCH CTU					
Other Retovent History, Including Premissing Medical Conditions (	C.D. allergies.				, Nore
rece, pregnancy, stroking and alcohol use, live/filliney problems, etc.)	Llan	G REPORTER  Name and Address	Sec confidential		
088					(b) (6)
OCT 13 2010		I=-			_
001 200	Hore	Phone #		E-creat)	<b>(b)</b>
C. PRODUCT AVAILABILITY		Z. Health Professional	7 S. Occupation	v vsames (scholler Jag	Manufecturer
	2				
Troduct Available for Evaluation? (Du not send product to FDA)	m/นัสโรการ)	5. If you do NOT went	your identity discisor		User Facility Distributor/meaner

A Description of the section of the	<i>CD</i> :	ER L LI	provide ONE No. 001	0-0291, Expires: 10/31/08
PICTURE STOLY ROOM	TARY reporting of product problems of use errors	and Trege unit sequence #	3863	-
4284527-4-00-01		DQR3		
A PATIENT DISCORDATION Patient (decution   2, Age of This of Event, or   3, See   4		EPRODUCTION  N. Marshestwer press place	ad lebeli	
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. Advance Event. Product Problem (9.9. defects/malfunctions)			•	
Product Use Breat Problem with Different Memeterbaser of Man	ne Madaire (2			
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☐ Life-threatening ☐ Congenite! Anomely/Birth ☐ Heapfieltzeton - Intilial or professes ☐ Other Serious (Important	ł 1	* *		Doesn't
Required intervention to Prevent Permanent Imperment Dermage (Dev	A Discussion of	Reason for Use (Indication)		Respired After
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02/22/2009 07/26/2009	62 0. Let 9	7 Expiration D		Apply
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misleading that you should be ashamed	1. Bread North			
your agency. After 25 years smoking 2 of conventional digarettes a day, I	2 packs 2. Common Dev	rice Nume	····	
to completely give up tobacco with th	30 1196 3. Memilianturer	North, City and State		
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FORM FDA 3580 (8/05) Submission of a report dess not constitute an admirelyn that medical personnel or the product caused or contributed to the event.

2009 5:12 PM FROM: Pax TO: +1 (800) 3320178

PAGE: 002 OF 003

Page 1 of 2

286386

Rendering Provider: Proctice

(b) (6) PA-C, (b) (6) F (b) (6)' MEDICAL CTR Phone: (b) (6)

Address: (b) (6)

Visit Date: Sunday, July 26, 2009

10985

home:

Patient: (b) (6)2

Medical Record #:

(b) (6) Sex: Male

Status: Complete.

Billing Provider (b) (6). Waiting approval by:

Visit Last Saved: 07/26/2009 11:37 ANL

CC / HPI:

pt states sx started soon after using electronic cigarrette

He presented with cough, it is located in the lung. It is described as constant and worsening @ night. The symptom started 1 weeks ago. Associated signs and symptoms include chills at times, dyspnea at times, sputum production and wheezing.

In addition, he presented with chest congestion. It is described as constant and painful. The symptom started t weeks ago. Associated signs and symptoms include sputum production,

### Current Medication:

Claritin-D 12 Hour 5 mg-120 mg Tab, 1 Tablet(s), PO, BID and for a total of 30.

Promethazine-DM 6.25 mg-15 mg/5 mL Syrup, 1 Teaspoon(s), PO, Q6-h PRN, for a total of 5 oz and \*\*\* PRN cough/congestion \*\*\*

Amoxicillin 500 mg Cap, 1 Capsule(s), PO, Q 8HR, 7 days, for a total of 21, start on July 26, 2009 and end on August 01, 2009.

Proventij HFA 90 mcg/Actuation Aerosol Inhaler, 2 Puff(s), INH, Q4-6h PRN and for a total of 1.

Morphine (Bulk) Misc and Misc (Non-Drug; Combo Route).

## Review of History

I reviewed the medical, medication and drug allergy histories.

### ROS:

Constitutional: The patient denied fever.

Ears/Nose/Throat/Neck: The patient denied stalgie and sore throat.

Respiratory: The petient complained of cigarette smoking and cough but denied asthma.

## Vital Signs:

data collected on 07/26/2009 10:11.33 AM by (b) (6) weight is 228 pounds clothed height is 5 feet 8 inches body mass index is 34.66 Kg/m2 temperature is 99.60F tympanic resolvation rate is 16 breaths per minute quiet

JUL 27 2009

heart rate is 80 bpm radial regular

blood pressure at Left Arm while Sitting is 120/70 mmHg

# MEDWATCH CTU

RECEIVED

JUL 28 CHUJ

Constitutional: general appearance, well nourished, well developed, in no acute distress. Ears/Nose/Throat: otoscopic exam, overall: external auditory canals clear and tympanic membranes clear, and oral cavity/pharynx/larynx, overall: oral mucosa clear, mobile tongue benign, tonsils benign, propharyngeal mucosa clear and no masses.

Respiratory: auscultation, left lower lung field: rhonchi (slight) and right lower lung field: rhonchi (slight); and, respiratory effort/rhythm, no retractions and normal rate. Cardiovascular: auscultation of heart, rate: regular rate.

Dx:

JUL 28 2009

http://local:59/WebBrowser/Prm.WebBrowser.DynamicHtmlPage.aspx?Key=7da57c52-77... 7/26/2009

TO: +1 fand taxpina byear too ob obs

Page 2 of 2





(UC) - C - URGENT CARE (466.0) - C - ACUTE BRONCHITIS

Rx:

pt states she can take phenergan/promethazine cough syrup
Amoxiciilin 500 mg Cap, 1 Capsule(s), PO, Q 8HR, 7 days, for a total of 21, start on July 26, 2009 and end on
August 01, 2009.
Promethazine-DM 6.25 mg-15 mg/5 mL Syrup, 1 Teaspoon(s), PO, Q6-h PRN, for a total of 5 oz and \*\*\* PRN
cough/congestion \*\*\*.
Proventil HFA 90 mcg/Actuation Aerosol Inhaler, 2 Puff(s), INH, Q4-6h PRN and for a total of 1.

### Services Performed:

(99203) URGENT CARE VISIT-NEW (94760) MEASURE BLOOD OXYGEN LEVEL (pre 97%, post 99%) (94640) AIRWAY INHALATION TREATMENT (xopenex 1.25)

Plan:

A return visit is indicated in 2 days if symp persist. He was advised to be on a Regular diet.

Plan Comment:

Quit smoking, discontinue electronic cigarrette, rewst/fluids (b) (6)

DSS JUL 28 2009

U! Individual Selety Report	
	Form Approved DME No. 0910-0291. Expires: 10/31/06 ARY reporting of Bes DMS eleterated on reverse.
	ARY reporting of seduct problems and
77 6735364-7-66-61	There errors DOAS sequence 4 8943
Adverse Every Reporting Program	on - Page 1
A Park H 1806 Sa to I	O SUMBLE RESIDENCE
1. Publish identifier 2. Age at Time of Brend, or 3. Bat 6. Weight	1. Horne, Birmann, Manufacturer (from areclas label)
(b) (6) Pote of Men. 310 h	a-diparetta medium were, admoke. net
Transfer 37 Years	7
Charles Barris Evaluation Selection (Selection County)	2. Dode or Americal Providency Rose
1. Adverse Svens Product Problem (e.g., defectatrafferential)	
Product Line Sever Problem with Officered Manufapherer of Same Manufape	
2. Outotenin Alfriquiri to Adverse Event (Chack of that apply)	
	3. Desce of Ven(if unknown, give dusting) horses for I. Event Absted After Use
(mental front	Out definate)  Chapted or Door Reduced?  of Vee ha Decent
Lite-investoring Congenital Anomely/Birth Defect	ASSIV
Homphalization - Initial or protonged	4. Diagnoste or Residen for Use (Indicator)
	B. Event Respected After Reinfredunction?
3. Date of Event (mm/gd/yyy) 05/18/2010 4. Date of the Report (mm/gd/yyy) 05/18/2010	#1 Van Dan Doment
5. Describe Evers, Problem or Product Use Error	Apply
slectronic cigarette purchased from	NZ Yes Ho Apply
esmoke.net was advertised as "not beying ANY	9. Noc e or Unique ID
carcinogens* and "all cartridges free rer; US materials" I visited the head location and	E PASHED LIBERTUAL DENVE
saw materials being shipped in from China	1. Srwd Rene
for use in the product and the a-vigaratte	www.e-make.pet
had obecamical taste to it and	2. Common Device Hare
malfuunctioned. This can be a serious health threat to the people seeking benefits from	1. Manufacturer Hanne, City and States
this product. FDA needs to investigate ASAP	easole.net in Lakewood MJ
	4. Model 9 Lot 4 S. Operator of Davisor
· · · · · · · · · · · · · · · · · · ·	Cetalog 0 Expression Date (nynydayyyy)
RECEIVED	Lay Used Paters
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	. x expense, one pag (manalyyyy)
MEDWATCH CTU	8. Is the a theyle-use Covice that was Reprocussed and Reused on a Polium?
	9. If You to Both No. 4, Enter Name and Address of Repropress
More	A to the second
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ANK CONTRACTOR ANK	Product names and therapy dates (archige freelinger of event)
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• 11 × 12	
More	
7. Other Relovant Mistery, Installing Presenting Medical Conditions (e.g., allergies, race, prepriery, areasing and discinct use, breaktings problems, etc.)	Hore I
ncc	1. Name and Address
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12V 0 0 2010	
MAY 20 2919	
More	7(6)((6)
C FRORBOTA ANAMOUN	2. Houlth Protocalonal 7 3. Compation 4. Also Reported to:
Product Available for Evaluation? (On not sound product to FDA)	Yes Manufacturer Mon-Menal Eb Manufacturer
✓ Yes	5. 8 you do NOT want your identity charlosed  be the manufacturer, place on "K" in this top:    Description   Desc
(mwathoo)	The second secon

105/50



For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

B5 Describe event or problems out rucd

quality control over the e-liquids. I'm just opposed to such a strong statement based on such little real evidence.

D88

Mail to: MEDWATCH

orFAX to: 1-800-FDA-0178

Sano Flanoro Lang

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

03/30/5011 00:25 18003320178 MED WATCH

,	DILL	CDER	
U.S. Department of Hostin and Human Bentost		Form Approved	t OMB No. 0810-0291, Expires: 10/31/0 See OMS paytoment on revers
A MANAGEMENT OF THE PARTY OF TH	ARY reporting of roduct problems and tuse errors		86387
A 6299519-4-00-81	m - vege 1 DQR	<u> </u>	
2. PATIENT CIFOR NATION  1. Patient Identifier 2. Age at Time of Event, or 3. Best 4. Walent	O SUSPECT PROBL		
(b) (6) One of Birth: (b) (6) Paredle (7)	1. Muna, Strength, Nanadae	and lucus broates and	, 
B. ADVERGE EVENT, PRODUCT PROBLEM, OR EBROR	12		
Chook all that apply:	2. Does up Amount	Frequency	Reute
1. Z Adverse Even Product Problem (a.p., defects/mellunctions)	91		
Product Use Error Problem with Different Maturiacisms of Same Madigine	62		
2. Customer Attributed to Advarse Evert (Check all that apply)	3. Dates of Lies/II unknown.	give durellon) from/to (or	5. Event Abeted After Use
Death: Directility or Permanent Correspo	beef activities		Stopped or Once Reduced?
Life-threatening Congenited Anomaly/Bitth Delect	-	•	Apply
Mospited patent in Indian or protonged Office Serious (Important Medical Greek	4. Diagnosis or Resson for	In (adenies)	Yes No Comm
Required Intervention to Prevent Permanent Impairment/Demage (Devices)     Date of Event (Imm/dd/yyyr)     4. Date of this Report (Imm/dd/yyyr)	4 1,1		Event Responsed After Reingraduation?
3. Date of Event (nm/dd/yyyy) 4. Date of thin Report (mm/dd/yyyy) 01/04/2009 07/23/2009			#1 Ves No Domen
6. Describe Event, Problem or Product Use Broom		. Expiration Day	Don Don Don
I bought the e-cigerette for the purpose of	100	H	B. NDC 6 or Unique 80
stopping smoking. When using the device I would become very dismy to the point that I	02	16	_ I RED F OF CHICAGO ED
would have to sit down. I have also	E GUSPEOT MEDIC	AL DEVICE	
starting having a very high white blood count that no one can find a reason for.	1. Brand Nama Smoke Everywhere.		
Also after stopping the use of the product I	2. Common Divice Harne		
have had a continued cough. I feel theme are all problems osused by the product.	3. Minufacturer Name, City	and State	
are are bronzens gaused by the broduct.	<b>Delatora</b>		
	4. Model 4	Let #	5. Operator of Device
RECEIVED	Coloro	Unknown Expiration Onto	Hoelift Professional
ILOLIVED	taknova	01/01/2009	(Lay Unam/Prisions
JUL 27 2009	Serial 9	Other #	Other:
202 21 1003	8. If Implemed, Give Dam (m	7. If E	eplanted, Give Date (minds/yyy)
MEDWATCH CTU		1	
MEDWAICHCIO	8. In this a Single-use Device	) Mai was Plaprodubled	i and Raused on a Patient?
	9. 2 Yes to limit No. 8, Enter	Manne and Address of I	aprocessor .
S. Relevant TestafLaboratory Data, Including Desce	1		
I have been having numerous blood tests over			
the past 9 months with white counts as high			
770	T. OTHER (CONCOM	EARTH MEANCAS	0000110-0
DOO	Product remove and therapy	Sees (EXCLUS PRAFFICE	RODUCES
JUL 28 2009			
	1 1		
7. Other Research Misters (mobuling flowed to Martin 1			•
<ol> <li>Other Relevant History, including Prestissing Medical Conditions (e.g., alargies, rect, prepriately, smoking and alcohol use, Syaridding problems, etc.)</li> </ol>	C REPORTER (Son o	antidantiality ser	from an track
Smoking, have devoloped a serve fatty liver and diabetes is very hard to control now.	(b) (6)		
For reasons maknown.			
•			
	Phon(b) (6)	(657 te	
C. PRODUCT AVAILABILITY	2. Health Protessions!? 3. C	our franch	4. Also Reported to:
Penduct Available for Evaluation? (Do not sand product to PDA)	I L.	dipietestor	Menufacturer
✓ Yee No Returned to Manufacturer en:	Nyou do NOT want your les to the mentiochers, piece:	entity disclosed	User Facility Distributor/Personer
ORM FDA 3500 (8/05) Submission of a report does not appearance or			Distribusor/emponer

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J.S. Department of Hasth and Harran Sandose	L Report	TADY manual	, 6, 5, 7, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1,	See CMB statement on reverse.
NICHALL SALES		TARY reporting of product problems and ct use errors		6388
A PATIENT INFORMATION  1. Patient identifier  2. Age of Time of Symptons of Birth:	Tit, or 1. Sex 4. Weight	D HUSPECT PROL	UC Ints)	
B ADVERSE EVERY PRODUCT Check of that apply:  1. Adverse Event Product Prob	FERRILL OF ERROR	2 Som or Amount	Frequency	Roun
Product Use Error Problem with  2. Outcomes Attributed to Advance Event	: Different Mamutacturer of Same Modic	ine de		
(Check of their apply)  Doeth:	Disability or Parmenent Damage	Salme of Ves (V unknown bank activate)	n, give duration) from to (or	6. Event Aband After Use Stopped or Dose Reduced?
(mar/dal/yyy)	Congenital Anomaly Birth Delect	<u> </u>	* *	Apply Apply
Mosphighty - Entitle or protonged	Other Serious (Important Medical S		- Alban Hadamirah	_ #2 Yen No Coment
Required Intervention to Prevent Parm	moral Impelment/Demage (Devices)	4. Diagnosts or Resson 6	or view (sreadesport)	6. Event Responsed After Reintroduction?
3. Date of Event (ministry)  07/23/2609	4. Date of this Region (mrs/dd/yyy) 07/23/1009			TO Yes No Donan'T Apply
6. Describs Event, Problem of Product Use		Q. Lot 0	7. Expiration Date	Doesn't
I have been using ele	stronic digarettes f	or n	a1	9, NOC 4 or Unique ID
about two months now no adverse effects. I	and have experience	a   -		
and I am confident it	is 100 times safer	3 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	ICAL DEVICE	
then emoking regular	cigarattes. I just b	Ope 1. Brand Name electronic cig	zette.	
the FDA realizes the	en that can be eased	ON 2 Common Daviso Name		
healthcare in the long	g term. If electroni	.C 3. Moradosturer Neme, C	•	
cigarettes are banned cigarettes are still	and regular coneccu	it totally wicked	errdara	
will be totally hypoc	ritical of the YDA t	Q L Model 6	Let #	5. Operator of Device
allow such a dangerou to be sold. Plesse st	udy and regulate the	Coloing #	Expiration Date (	Mesith Prefessional
e-cig ingredients to do not isse an outrig	protect our bealth,	Dut Serial 8	Other 6	Other:
		6. If Implemed, Give Bas	a (mmkidiyyyy) 7. W.E.	spleniad, Give Date (nam/50/3333)
		O. Is this a Bingle-use De	evice that was Repressed	d and Roused on a Patient?
		Yes No		
	Í	1. 17 Yee to Harry No. 4, E	riser Heimo and Address of	Linkudesendi
n/a	ECEIVED			
DSS	JUL 27 2009	Product names and the	GENTANTE DE LUICAL	
JUL 28 2009 ME	DWATCH CTU			,
7. Other Relevant History, inchaffing Press (800, programcy, ampking and alcohol use	sirting Medical Conditions (e.g., allegis	M. C. DEPARTSOL	Sec considenti dily	reten na backa
former tobacco smoker free.	•			
			Te=	4
		Phone 6	(6)	A company of the comp
C PRODUCT AVAILABLETY	and mind in SDA	2. Handle Professional?	a. Gotupalion	4. Also Reported to:
Preduct Available for Evaluation? (Do not	•	& Hyou do NOT want y	our Monthly disclosed	User Facility
✓ Yes ☐ No ☐ Retained to	Manufacturer on:		Name of A. (a the per-	Distributor/Amportar

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

04/05/2011 01:46



**W**ATCH

386388

B5 Describe event or problem continued

product that can help millions of Americans stop smoking, or continue to "vape" in a safe way.

DSS 3009 28

Mell to: MEDWATCH

SROG Flahers Lane Rockville, ND 2082-8787

or FAX to: 1-800-FDA-0178

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

MANAGER AND THE PROPERTY OF THE PARTY OF THE

MED WATCH

CONKIL

FORM Approved: OMB No. 0810-0291, Exptras: 10/31/08

See OMB statement on raverae.

TARY reporting of

		product problems and it use errors CDTR	Triagge unit 38	6385
0206523-1-00-01	ARTERTO MUNICIPALITY		andraum . 30	080
Adverse Event Reporting Program A PAINGNEDWORK ATTOM		O SIGNED FROM	CT16	
1, Puriors Igentifier 2. Age at Time of Even	t, or 2. Sex 4. Weight			NOT -Health E-Cigarette
(fall) Dutte of Birth:	Female 100 lb	Smalth E-Cigare	median	MADE -Health E-Cidexette
in confidence (b) (6)		12		
B AT 76 HOSE EVENT PRODUCT	PROBLEM OF CHAOR	2. Dose or Amount	Proquency	Roule
Check will think adopty:  1.   Advance Event Product Proba	ions (e.g., delecto/malkarciions)	/1 10 mg	regular	iy- po
	Different Mynutesturer of Sarea Modicine	12		
2. Outgoinne Attributed to Adverse Event				
(Check of that apply)	□ Brook Brook Brook	2. Detre of Use/ff unknown bas retirate)	, give duration) fram/to for	5. Event Abated After Use Stopped of Dose Request?
Deeth: (min/65/yyy)	Disability of Permanent Derrege	#1 07/09/2009	07/24/2909	#1 Yes No Denomi
Ulti-Presidenting	Congenite: Anomally/Birth Detect  Other Serious (Imponent Medical Events	. 2	• •	TO DOMENT
☐ Hospitalisation - Initial or prolonged ☐ Required Intervention to Provent Permit	-	4. Diagnosis or Resson to		8. Every Regress and After
2. Date of Event (metallyyy);	4. Date of this Report (newdolyyyy)	I smoked and )	14564 151	Reintroduction?
07/22/2009	07/24/2009	e2		P1 Yes No Z Doesn't
5. Detarite Event, Problem or Product Use	Ener	8. Lot #	7. Expiration Date	82 Yes No Doment
The event I would like		a1	<b>a</b> 1	A. NDC # or Unique 10
great significance in		a	<b>#2</b>	
SMOKING: I did so b   cigarettes. I get to	by using electronic	C SUSPECT MEDIC	AL DEVICE	
smoking that I like, w		1. Brund Mame Realth K-Cigare		
harmful byproducts.	Do I want PDA	2. Caramon Device Name		
regulation to make sur safe as they can be?	TRS Should you ban	3. Manufacturer Name, Ch	N and Stars	
these outright when so	many people stand to	Chien	,	İ
	this witch hunt and	4. Model 6	Lote	5. Operator of Cavica
work with suppliars.		7		Houlth Proressional
		Catalog #	Expiration Date /	
		Serial #	Other &	Otner:
REC	EIVED			
	/ <u> - </u>	c. If implement, Give Date	(hunvaalvyyy) 7, M E	eplanted. Give Date (mm/dic/yyyy)
l aul	27 2009	0, is this a Single-use De-	rice that was Repromuses	d and Revised on a Petions?
		Yes Z No		
AACT)A	ATCH CTU TO		to esercish bna empli ne	Reprocedue/
C. Relevant Temp/Leberatory Dee. Institution		7		
_		C STUEB MAN	DUITANT I MEDICAL	SECONO
DSS JUL 28 2003			apy dates (arcives realis)	
DOO				
na 29 2003				
JOE TO SEE	Mot	<u> </u>		[ <u>**</u> -1.
7. Other Relevant History, Including Proces	riating Medical Combiners (e.g., Alergius,			More
race, pragnency, emoking and alcohol day	ack of cigarettes a da		es confinentially se	J. Proc. St. D. J.C. N.
for 13 years, and now		y (b) (6)	<b>2</b> 00	
			T <sub>E</sub> -rea	
	Mos		(b) (	(6) <u> </u>
C PRODUCT AVAILABILITY		2. Neeth Professional?	3. Cacupaton Contraser/Non-Re-	A. Also Reported to:
Product Available for Evaluation? (Do not	auns product to FDA)	S. If you do NOT want yo	<u> </u>	User Facility
Yes No Returned to	Monufacturer on:		ur roundry graceouse shape an "X" in this beac	Distributor/Importer

	1/1-	CUK	LI		
Individual Safety Report  1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	VOLUNTA	RY reporting of duct problems and	Triage tink	8649	in B-Odfan, Beginse: 10/31/0 OMR attatement on reverse RCS
A CONTRIBUTE INSCRIPTIONS  1. Patient Identifier 2. Age at Time of Event, or 3. See	4. Weight	1. GBS/ECITORO 1. Name, Strangth, Man	S JCT <sub>[S]</sub>	olj	
h confidence Sh (b) (6)	or	91	······································		
B. ADVERBLEVENT, PRODUCT PROBLEM OF EYRO Chack As That apply:		2. Does or Attrourt	Frequen	7	Reside
Adverse Event     Product Problem (e.g., defects/mafunction     Product Use Error     Problem with Offerent Management of 3	raj Ioma Madicina	21			
Gutcomes Attributed to Adverse Event (Circce all thet apply)		2. Decisio de uso per unione	own, give aunation) from/to (	or 6. Even	Abated After Use
Disability or Permanent    Disability or Permanent	- 1	(test settmete)	••	1 -	ed & Down Reduced? (es No Down's Apply)
☐ Life-Birestening ☐ Congenius Anomalytiss ☐ Hospital/Imitins - initial or prolonged ☑ Other Serious (Importer	· · · · · · · · · · · · · · · · · · ·	12		- 12 D	Tee No Coept
Required Intervention to Prevent Permanent Impairment/Demage (Dr. 3. Date of Strans (mm/gd/yyyy)  4. Date of Strans (mm/gd/yyyy)  4. Date of Strans (mm/gd/yyyy)		4. Diagnosis er Resech	for Use (inchalibre)		Responsed After oduction?
07/27/2009 07/27/2009	100)))))	12		- 0	Tee No Desem
5. Describe Event Problem or Product Use Error No adverse reaction. Am using this a	venue to	G. Lot P	7. Expiration Date		res No Desert
voice my disgust with the FDA and it announcement on s-cigs. Talk about	:•	k5	•7	9. NDC 1	er Unique 10
biased: [[]] So, I guess there truly adverse reaction being posted here.	is an	5. SUSPECT VL	HONVEG LADIK		
FDA!!!! The e-cig isn't being tar childrenthe online sites specific	geted to	a - C1g 2, Commen Device Non	* Flar	Poster	CIENCETTE
state this. And guess what?? They're lot of adults who want flavors that	are a	3. Marsulijaturar Hymne,		rai.vic.	C. IENNE TE
think are there to be attributed to	oker of	4. Madei p	Lote		10 000
nearly 30 years, I'm thrilled to have the e-cig. It's helped me quit		501			5. Operator of Dovice  Health Professional
cigssomething even Chantiz couldn		Calaing #	Espiration Date	) (mmvacyyyyy)	Lay User/Pottent Other:
accomplish. Actually, I'm not oppose the FDA wanting to exert some	osed to	Seriel #	Other &		
		d. Il implement, Give De			re Date (mm/dayyyy)
		Yes No	evice that wee Represent		
5. Retowant Topis/Leternitory Data, Including Dates	Mose	N. 17 796 IO BORT 150, 8, E	inter Hame and Address :	ii Reprobase	1
RECEIVED					
JUL 2 2009			DIVILLANTE MEDICA FROM dates (SECUCIO FROM		
MEDWATCH CTU			•	DV	- 2000
	More			JUL 8	
<ol> <li>Other Relevant Mistery, including Presiding Mistigal Conditions (e. nace, pregramey, analysis and score) use, translating process, etc.</li> </ol>	anorgios.	G. REFORTER (S	ee contgrinality s	etti in ee i	Maga Maga
Sealing Property and Company of the		(b) (6)			
	Stars	Phone # (b) (6)	B-m	eŭ .	
Product Available for Evaluation? (De not send product to FDA)		2. Hophis Professional?	3. Occupation	4	After Reported to:
Vcs No Palured to Manufacturer on:	(פיניים	5. If you do NOT want yo to the prenufacturer,	our Montey discioused place an "X" by this box;	7	User Facility Distributor/Impaner
FORM FDA 3500 (8/05) Submission of a report does not				Sused or cor	

04/05/2011 01:46

18003320178

For VOLUNTARY reporting by health professionals of adverse events and product problems Internot Submission - Page 2

### B5. Describe event or problem continued

quality control over the e-liquids. I'm just opposed to such a strong statement based on such little real evidence.

DES JUL 29 2009

Mail to: MEDWATCH

orFAX to:

1-808-FDA-0178

8600 Fishers Lane Rockville, MD 20052-9767

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

PAGE 15/37



VATCH

donals of adverse events and product problems: Submission - Page 2

# B5 Describe event or problem continued

sorts, including nicotine, which is a known toxin. It is also known that air pollution affects people differently depending upon their health status and sensitivity. The hypothesis being advanced by proponents is that there are no acute or chronic health effects or air pollution impacts if these devices are used in currently smoke-free areas. So a research program would start by collecting multiple samples of each of the 2 dozen or so brands currently being marketed and analyzing the E-liquids in them. Next, multiple tests would be run on the devices when they are smoked under controlled circumstances in an experimental chamber to determine emission factors for each of the components of toxicological interest, including carcinogenic potency. In this manner, the standard mass-balance model can be used to predict their concentrations in occupied spaces. Next, panels of healthy nonsmokers and sensitive nonsmokers would be employed to test the odor. irritation, and cardiorespiratory impacts of exposure to E-cigarette vapor, using standard butanol wheel, eye-blink, pulmonary function, and heart rate e-cigarette vapor, using ecanuary butanor wheel, eye-ofink, purmonary function, and heart rate variability tests. This would allow public policy to be based on science, rather than speculation. Of course, such studies would involve multi-million dollar research grants and multidisciplinary researchers involved. Then the peer-reviewed and journal-published data would be reviewed by impartial expert panels of national and international agencies. I submit that this would be the intelligent way to make a public health policy decision involving exposure of infants, children, elderly persons, and those with cardiorespiratory conditions to products of currently unknown composition and unknown interaction with the hundreds of existing air pollutants in indoor air. Until this is done, it is only prudent to keep E-cigarettes out of smoke-free zones. (b) of smoke-free zones. ot smoke-iiee zoner. (6)

DSS

MAR 1 9 2010

MAIL to: MEDWATCH or FAX to: 8600 Fishere Lane Rockville, MD 20882-8787

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



.UNTARY reporting of mis, product problems and roduct use errors DOGS

Form Approved: OMB No. 09 (0-0291, Expires: 12/31/2011 See OMB statement on reverse.

oduct problems and use errors DORS	Triage unit	41124
_dCDEK		1427-
D SUSPECT PRODU	(*)	
1. Name, Strangth, Manufact	uter (from product jabel)	
MS ZWW	CHE	
#2		
2. Dose or Amount	Frequency	Route
*1 4. 1		
#2	] [	
3. Dates of Use (if unknown, g	ive dutation) kamfo (or	S. Event Absted After Use
19,10		Stopped or Date Reduced?
m /0 c / C		Apply  12 Yes No Dosent
4. Diagnosis or Rosson for U	e (Indication)	A Powert Responsance After
MEUNG- S	CRE	Reintroduction?
PTABAT	- SCRE	at Wes No Doesn't
	Expiration Cate	42 Yes No Doesn't
82		P. NDC # or Unique ID
E. SUSPECT MEDICA		
		INTERNATION
2. Common Device Nema		
3. Manufacturer Name, City of	2 PUFF	E K
1	ELESAV	CANADA
4. Model #	Lot#	S. Operator of Device
Catalog s	Expiration Date (nm	Hesith Protectional
Secial #	Other #	Lay User/Patient
	Lugar P	
6. If Implement, Give Date (mm.	You'yyy) 7. II Exp	lanted, Give Dess (mm/bd/yyy)
6. In this a Single-sus Device	that was Roprocessed ar	id Reused on a Patient?
B. If Yes to from No. 8, Enter M	eme and Address of Rep	rocettor
·		
F. OTHER (CONCOMIT	CANTO MEDICAL DE	0000000
Product names and therapy d		
		(avant) D22
		JAN 1 2 2011
		AND TE CALL
G. AEPORTER (See or	intidentiality section	n 20 <b>b</b> ack)
1. Nettle and Address		
The state of the s		
Phone (	(b) (6), E-moli	
2. Health Professions/? 13. Oc		4. Aise Reported to:
TOS KAE	RETURED .	Manufacturer

S. If you do NOT ward your identity disclosed

distinction of a secret draw over constitute an arimisation that reading contributed or contributed to the event.

to the manufacturer, place on "X" in this box:

User Facility

	. 7228144-X-30-81 rodu
	) hage
	A PATIENT INFORMATION
	1. Ontion I decided
	(b) (6) Asia.
	in confidence ig
	B. ADVEASE EVENT, PRODUCT PROBLEM OR EAROP
	Check of that apply:
	1. Adverse Event Product Problem (e.g., dolecto/mellunctions)
	Product Use Error Problem with Different Manufacturer of Some Medicine
	Otherwise Attributed to Adverse Event     (Check of that apply)
	Death; Disability or Paragraph Certage
	Life-threstening Congenital Anomaly/Birth Delaci
	Hospitalization - initial or prolonged Other Serious (Important Medical Events)
	Required Intervention to Prevent Portugues Impairment/Damage (Devices)
	Date of Event (mm/od/yyy)     4. Date of this Report (mm/od/yyy)
ı	S. Describe Evern, Problem or Product Use Error
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-	6. Relevant Teets/Leberstory Date, Including Dates
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ı	ロログロマ
-	JAN 12 2011
I	
	MEDWATCH CTU
1	**************************************
ŀ	7. Other Relevant History, including Presidenty Nedical Conditions (e.g., alterples.
	race, pregnancy, smoking and alcohol use, livertidney problems, etc.)
	İ
-	

C. PRODUCT AVAILABILITY

☐ Yes ☐ No

ENDM ENA JENN / I POL

Product Available for Evaluation1 (Do not send product to FDA)

Anturned to Manufacturer on: \_\_

(mmtjolynyn)

U.S. Department of Heelth and Harbatt Services

18003320178

VOLUNTARY reporting of se events, product problems and

Form Approved: OMB No. 0910-0291, Expires: 10/31/06 See OMB elatement on reverse.

Individual Safety Report	VOLUNTARY re			F-1	V 1 .F (10)	7	
	ne events, product p product use err		Triage unit	49	69	41	
	: Submission - Pa					11	
A PATISM INFORMATION		MORE TOBACUS					
		me, Strength, Mahvins		oduct laber)	· · · · · · · · · · · · · · · · · · ·		
(b) Consider Consider	226 B	•		•			
in conditiones 87 Years	or						
8 ADVERSE EVENT - RODULT FOURLED OR LINES. Check at the apply:	2.	Dods or Afficient		requestry		Route	
1. Adverse Evens Product Problem (a.g., defects/meriumstons	<sub>1)</sub>						
Product Use Error Problem with Offerent Manufacturer of Se	rine Mucholmu #2			<del></del>		7	
2. Outcomes Attributed to Adverse Event (Check all the) apply)	3. De	tee of Use(# unknown,	give duretion)	framte (or	5. Even A	baled After U	
Coath: Disability or Permanent D	l l be	et Bellmilto)			Stoppe	i or Dees Red	
Life-firestening Congented Anothely/Birth	Defect #1		<del>-</del>		an Uva		Apply
Hospitalitation - initial or protonged Other Serious (Important		ephagis or Region for	lles /betset/b	-1	42 Q Y	• 🗆 No [	Doesn't Apply
Required Intervention to Prevent Permanent Impairment/Damage (Dev	Access)	all-design on several for	Cas Indicate	·y	6. Event R	supposed At	to r
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/d 08/14/2010 08/14/2010	agyyyyi ag		•			m 🗌 No (	Doesn't
08/14/2010 08/14/2010  5. Damoribe Every, Problem or Product Use Error	e. Lo		7. Expiration	Dan	#2   Va	a No	Coeso'i
I WANT TO REPORT ADVERSE EFFECTS OF	E CIGS.		#1			or Unicom 10	Apply
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PHYSICAL AND DOCTOR ASKED WHEN I HAD	HAD A 2. Co	minon Davico Mame		<del></del>		•	***
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THE DOCTOR MY RESTING HEART PATE WAS BEATS A MINUTE. ALL TEREE TIMES. S	INCR I	odel •	Lot		1	5. Operator o	Device
DENIE A MARKA AND AND MARKET BY	377		1			Mastin P	
STARTING REAL CIGS AGAIN MY HEART BE	A2 13		F				rofessionsi
BACK TO 65 PER MINUTE. I CAN ONLY CO	ONCTODE C	Anking 4	Ехріг	HON Date (#	MAZINANY)	Lay Use	
	OMCLUDE CA	Plaking # orini #	Expire		meddyyyy)		
BACK TO 65 PER MINUTE. I CAN ONLY CO	OMCLUDE MY HEART	orinā d	Other	,		Lay Use	n/Patient
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BACK TO 65 PER MINUTE. I CAN ONLY CO	OMCLUDE MY HEART  6. II	implement, Give Date (	Cifter (mm/ssSyyyy)	7, K Es	planted, Giv	Lay Use: Other:	r/Pathant
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FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical parameter or the product caused or contributed to the event.





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representation of adverse events and product problems termet. Submission - Page 2

B5 Describe event or problem continued

CONTRIBUTED TO BELLS PALSY -NO WAY TO KNOW-. THE OTHER THING HAPPENING WAS A CONSTANT LOOSE BOWEL SYNDROME. I AM WRITING THIS BECAUSE THE BLOGS ON INTERNET MUST ALL BE CONTRIVED BY THE E CIG MANUFACUTURES BECASUE I COULD FIND NO ADVERSE EFFECTS ON LINE MAY CONTACT ME AT

(b) THANK YOU HOSPITALIZITION WAS FOR THE BELLS PALSY

DSS

AUG 16 2010

Melf to: MEDWATCH

or FAX to: 1-490-FDA-0178

5600 Fishers Lane Recivitie, MD 20882-9787

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

enogm/soudreid

MED WATCH

KY reporting of duct problems and

Triage unit 42463 product use erides Internet Submission - Page 1 Adverse Event Reporting Program A PATIENT DECRMATION P F ISPECT PRODUCTES 1. Heres, Strongth, Manufacturer (lipp: product lacel) 1. Pottert identifier (2. Age at Time of Event, or (b) (6) 4. Weight 2-Cigarette Health E-Cigaratt (b) (6) Female (b) (6) D MAIN ADVERGE EVENT PRODUCT PROBLEM OR EPROR 12 Dose or Amount Route Prequency Check all that copy Inerd cenerth Product Problem (e.g., detectamelfunctions) Product Use Effor Problem with Offerent Menutecturer of Sume Modicine #2 Oceannes Attributed to Adverse Event (Chack all that apply) 3. Dates of Use of unknown, give dumition) from/to for 5. Event Abeled After Use lopped or Done Reduced? Death: \_ Disability or Permanent Demage et 🛮 Yos 🗌 No 🔲 Docan'i (mm/dd/yyyy) 07/19/2010 at 07/15/2010 Apply Life-threatening Congenital Anomaly/Birth Delect #2 Yes No Doesn Other Serious (Important Medical Events) Mespitalization - wittel or prolonged 4. Diagnosia or Resson (or Use (Indication) Required intervention to Prevent Permanent Implement/Damage (Dankse) 5. Event Responsed After 81 4. Date of this Report (mm/dd/yyy) 3. Date of Event (mm/dd/yyyr) 91 ☐ Yes ☐ No ☐ Dosal 07/29/2020 07/10/2010 22 #2 Yes No Domen' S. Let I 7. Expiration Date 5. Describe Event, Problem or Product Des Error at nome After using a e-cig, felt very sick and 8. NDC 0 or Unique ID dizzy them started sweating badly. felt the 12 none need to go to sleep early and while in bad E RUSEBOT MEDICAL DEVICE started to vomit. 1. Bradd Name 2. Common Device Name 3. Manufacturer Name, City and State 5. Operator of Daylee 4. Model # Lot # Health Professions Expiration Date (min/dd/yyyy) Catalog # RECEIVED Lay Veer/Patient Other: Other # Garlet d JUL 21 2010 5. W implement, Give Date (mm/dd/yyyy) 7. # Explanted, Qive Date (mm/td/yyy) 8. Is this a Single-use Device that www Reprocessed and Reused on a Patient? MEDWATCH CTU Y68 No 9. If Yes to from No. 8, Error Name and Address of Reprosessor More 8. Relevant TestarLaboratory Data, Including Dates DSS OTHER CONCOMITANT MEDICAL PRODUCTS duct names and therapy dates (suckeds transment of event) JUL 21 2010 Moze Mere Other Relevant History, Including Pressisting Medical Conditions (e.g., ellergies, rico, pregnancy, anothig and alcohol use, liverlidiney problems, etc.) G. ARP DRIER (See confidentiality section on back) 1. Name and Address amoking (b) (6) 5-mell More 2. Health Professional? 3. Occupation Also Reported to: C PRODUCT AVAILABILITY Ton I No Manufacture/ Product Available for Evaluation? (Do not send product to FDA) User Facility

FORM FDA 3500 (8/05)

Assumed to Manufacturer on: \_

(mm/dd/yyyy)

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

If you do NOT went your identity disclosed

to the menufucturer, piece on "X" in this box:

U.S. Department of Health and Human Services

# MED WATCH

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

(b)(6)

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Required Intervention to Prevent Permanent Impairment/Damage (Devices)

Use of the e-cigarette and possible link to pleurisy. Pt has been a 2+ pack a day cigarette smoker for the past 30 years. decided to quit, and was using the e-cigarette thinking it was a safe

alternative and a way to help quit smoking. Pt had been using the e-cigarette for about

cigarettes. Pt started to have sharp pains in chest for a couple of days when pt would breath in and out. Pt went to my PCM and was dignosed with pleurisy and fluid in lungs. The e-cigarette uses water vapor.

 Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) NKDA, White female, occasional alcohol use. 2+ pack a day smoker for past 30 years. About 3 months ago quit using "real"

3 months, without using any "real"

A. PATIENT INFORMATION 1. Patient Identifier | 2. Age at Time of Event, or

**Outcomes Attributed to Adverse Event** 

Hospitalization - initial or prolonged

5. Describe Event, Problem or Product Use Error

6. Relevant Tests/Laboratory Data, including Dates

MRI 05/04/2011

(mm/dd/yyyy)

(b) (6)

In confidence

Check all that apply 1. Adverse Event

(Check all that apply) Death \_\_\_

Life threatening

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

05/04/2011

product

Internet Submissi

4. Weight

More

More

More

(mm/dd/yyyy)

3. Sex

Product Problem (e.g., defects/mellunctions) Product Use Error Problem with Different Manufacturer of Same Medicine

Z Female

Disability or Permanent Damage

Congenital Anomaly/Birth Defect

4. Date of this Report (mm/dd/yyyy)

05/09/2011

Other Serious (Important Medical Events)

Male

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

luct problems a	nd	FDA USE ONLY
se errors /	Triage unit	153131
- Page 1/10	QRS	
D. SUSPECT		- hadi
s-cigarett	Manufacturer (from product le	ukn
#1		
#2		
2. Dose or Amor		
#1 aprox 2 c	artriges	po po
#2		
best estimate)	mknown, give duration) from/to	(or 5. Event Abated After Use Stopped or Dose Reduced?
#1 02/01/201	05/09/201	
42		[ ] [ ] Door
Diagnosis or Rea	ison for Use (Indication)	Apply Apply
smoking c	essation aid	8. Event Reappeared After Reintroduction?
#2		#1 Yes No Does
. Lot#	7. Expiration Date	Apply Does
ukn	41	Apply
#2		9. NDC # or Unique ID
	MEDICAL DEVICE	unk
. Brand Name	REDICAL DEVICE	
ukn	n 188 <del>1 – All Marian de La Roman de la Rom</del>	PP - PPP-PP - PPP - PPP-PPP - PPP-PPP-P
Common Device	Name	
<u>e-cigarette</u> . Manufacturer Nar		
. Model #	Lot # ukn	5. Operator of Device
Catalog #	Expiration Date	Health Professions (mm/dd/yyyy)  Z Lay User/Patient
Serial #	Other #	Other
If Implanted, Give	Date (mm/dd/yyyy) 7. If	Explanted, Give Date (mm/dd/yyyy)
le this a Cinala us	Doube that was B	
Yes N		ed and Reused on a Patient?
If Yes to Item No.	B, Enter Name and Attress	Re riceser
	М	AY 11 2011
		·
	MEDI	WATCH CTU
OTHER (CO	COMITANT) MEDICA	PRODUCTS
roduct names and	herapy dates (exclude treatm	ent of event)
		·
DEDODES	/2	More
Name and Address	(See confidentiality se	ection on back)
reant and Address		(b) (6
one#	l F-mai	
 Health Professional	?  3. Occupation	(b) (
✓ Yes No	Other Health	4. Also Reported to:
- Indian		Manufacturer
iyou do NO I want	your identity disclosed	User Facility

Yes No Returned to Manufacturer on: FORM FDA 3500 (8/05)

cigarettes and started

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

C. PRODUCT AVAILABILITY

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

to the manufacturer, place an "X" in this box:

Distributor/Import



4533

TO STANSON THE .

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 4

B7. Other relevant history, including preexisting medical conditions continued

using e-cigarette.

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

1. 1000 不是的**对性**1.

or FAX to: 1-800-FDA-0178

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

WINDSHIP .

~ \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

MEDWATCH

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

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

FDA USE ONLY

A PATIENT	INFORMATION	NAME OF TAXABLE PARTY.		2. Dose o	or Amount	Freque	ncy R	oute
	er   2. Age at Time of Event	or 3. Sex	4. Weight	#1				
b)	Date of Birth:	☑ Female	102 <sub>lb</sub>					
	51	_	or 46.4 kg	#2				
In confidence		Male Male						
B. ADVERSE	EVENT, PRODUCT	PROBLEM OR E	RROR	3. Dates of for best e	Use (If unkno	own, give duration		<ol><li>Event Abated After Use Stopped or Dose Reduced?</li></ol>
Check all that appl				#1 10/08/	Activities and the second			#1 Tyes No Doe
1. Adverse Ev		m (e.g., defects/malfund	Control of the contro	#2 10/13/				App
of the Control of the	Error Problem with Di	Merent Manufacturer	of Same Medicine			for Use (Indication	07)	#2 Yes No Doe
<ol><li>Outcomes Attr (Check all that)</li></ol>	ributed to Adverse Event apply)			#1	0 01 11000011	The was grown		8. Event Reappeared After
Death:		Disability or Permanent	Damage	No.				Reintroduction? #1 ☐ Yes ☐ No ☑ Dos
☐ Life-threater	(mm/dd/yyyy)	Congenital Anomaly/Bir	rth Defect	#2				App
Charles and Charle	ion - initial or prolonged			6. Lot #		7. Expiration	Date	#2 Yes No Doe App
	tervention to Prevent Perman		Control of the Contro	#1		#1	1	9. NDC # or Unique ID
. Constitution		. Date of this Report (		#2		#2		Commission of the Const. St.
<ol> <li>Date of Event</li> <li>10/02/201</li> </ol>		. Date of this Report (	,, 000 / / / / /	E. SUSI	PECT MED	ICAL DEVIC	E	
	t, Problem or Product Use	Error		1. Brand Na	ame		THE REAL PROPERTY AND ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY AND ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PERTY ADDRESS OF THE PE	
I read an	article on line ab	out how to quit	smoking	Direct	ecig.com			
with an el	ectronic cigarette	. In this artic	le the	2 Common	Device Nan	ne		
smoking th	is e-cig. There wa	s a link to buy	one for	e-cig	. Device Hall			
shipping c	costs, only \$4.95. order, to try it. I	You got a month	s supply					
	order, to try it. I an order now page					City and State 2338 immoka	lan vd	#410
was advert	ising on this page	to buy other f	lavors and			34110-1445		#4+2
	other than that, i send it to you. I					The Paris	A FFT	The .
Oct.8 but	couldn't use it un	til I charged i	t. I had to	4. Model #	E EA.	- Cot# F	W Lond	5. Operator of Dev
mess with	the battery and ch start charging eve	arger for 20 mi	nutes to			Alone T.O.	NO. COL	Health Profession
gec ze co	State charging eve	Ly came a caree	1	Catalog	#		n Date (mm/c	dd/yyyy) 🗸 Lay User/Patien
								Other:
6. Relevant Tests	s/Laboratory Data, Including	ng Dates		Serial #	To de la company	Other#		5.3
	1000000000000000000 U 00000000000000000	**************************************		Oct.id.	200220000000000000000000000000000000000	0.010.62	I be to	No.
							la ve v	
				6. If Implan	ted, Give Da	te (mm/dd/yyyy)	7. It Expla	anted, Give Date (mm/dd/yy)
				8. Is this a	Single-use D	evice that was F	Reprocessed	and Reused on a Patient?
				Yes	-	THE RELL SHEET STATE OF		May = 50 / 50 50 50 50 50 50 50 50 50 50 50 50 50
			9 4	9. If Yes to	tem No. 8, En	ter Name and Add	Iress of Repr	ocessor
7. Other Relevan	t History, Including Preexis	sting Medical Condition	ons (e.g.,					
allergies, race,	pregnancy, smoking and alc en a smoker for 30+	cohol use, liven/kidney p	roblems, etc.)					W 0 0 1 1 0 W 0
4 Have bee	A DWINGE TOT 304	200001		AND DESCRIPTION OF THE PARTY OF	STATE OF THE PERSON NAMED IN	OMITANT) M	A STATE OF A SECRETARY	STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET,
				Product na	mes and the	rapy dates (exclu	uae treatmen	t or event)
				G. REPO	RTER (Se	e confidentia	lity sectio	n on back)
				1. Name an	EXPERIMENTAL PROPERTY AND THE			- Value of the second
The Street of Street Street Street	T AVAILABILITY		医多种溶解的 单	Name:		(b) (6)		
	le for Evaluation? (Do not s			Addres				
✓ Yes N	Returned to Manufa	acturer on:	n/dd/yyyy)		(b) (6)			(b) (6)
D. SUSPECT	PRODUCT(S)			City:	(5) (0)		State	(6) (6)
A CONTRACTOR OF THE PARTY OF TH	th, Manufacturer (from prod	uct label)		Phone #			E-mail	(b) (6)
#1 Name: Dire			1					(b) (d)
Strength: 16:	mg Directecig.com			2. Health P	rofessional?	3. Occupation		4. Also Reported to:
	Directedig.com			but he ablican		Accession to the second	Desfersional	Constitutes of the Association and the Constitution of the Constit
				Yes	V No	Non-Healthcare	Professional	[ Wauntacinial
#2 Name: Strength:				5. If you do	Second Contract Contr	ur identity disclos	A SUL AND HAVE A	User Facility

U.S. Department of Health and Human Services

The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)

# For VOLUNTARY reporting of adverse events and product problems

Page 3 of 3

435361

5.5. Describe Event or Problem (continued)
After charging it, I put the nicotine "filter" on the end. There's no taste to this. Only an after caste that lingered for hours. The article said that the ecig looked, tasted and satisfied your craving
ust like a real digarette without all the harmful chemicals. At first I thought I just needed to get
used to it being different, but I asked my adult son to try it and he had no idea it was supposed to be menthol and told me several hours later he still had the after taste. I was still craving a real
igarette and bought some. And smoking them didn't really cover the taste from the ecig. I got so
rustrated with it, I put it in the recycling. On Oct. 20th, I received an email from directecig
saying my order was shipped and the cost was \$99.95. I emailed right away and told them I didn't order
mything. That's when they informed me that I had signed up for some sort club and that they were going
to ship me more cartridges every month. In the course of emails that followed, they sent me a copy of
their terms and conditions page that I was unaware of. I immediately opted out on line when I found it

menthol and told me several hours later he still had the after taste. I was still craving a real cigarette and bought some. And smoking them didn't really cover the taste from the ecig. I got so frustrated with it, I put it in the recycling. On Oct. 20th, I received an email from directecig saying my order was shipped and the cost was \$99.95. I emailed right away and told them I didn't order anything. That's when they informed me that I had signed up for some sort club and that they were going to ship me more cartridges every month. In the course of emails that followed, they sent me a copy of their terms and conditions page that I was unaware of. I immediately opted out on line when I found it. I looked at my bank account on line and there was a hold for \$99.95 on my account which disappeared, then reappeared the following monday. I tried to track the fedex number they sent me with invalid coming up. I got a package by usps and sent it back. I filed a complaint with the BBB in which I said this tasted tainted (my first realization). That's when I fished the ecig out of the recycling (the battery makes it harder to recycle it) and came to your website. If you would like to look into this,
B.6. Relevant Testa/Laboratory Data, Including Dates (continued)
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

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

# **MEDWATCH**

The FDA Safety Information and Adverse Event Reporting Program For VOLUNTARY reporting of adverse events, product problems and product use errors

Internet Submission - Page 1

	CAN CHICA ENGLISHED	
	FDA USE ONLY	
nage unit	LIGHT	

A. PATIENT INFORMATION	D. SUSPECT PRO	DUCT(S)	
Patient Identifier 2. Age at Time of Event, or 3. Sex 4. Weight	1. Name, Strength, Manu		(abel)
Date of Birth: Female ib	E-Cigarette		Njoy
In confidence (D) (O)  Make or kg	NCig -on batte	ery-	
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	2. Dose or Amount	Freque	ency Route
Check all that apply:	81		•
Adverse Event     Product Problem (e.g., defects/melfunctions)  Product Use Error    Problem with Different Manufacturer of Same Medicine	100		
2. Outcomes Attributed to Adverse Event	#2		
(Check all that apply)	3. Dates of Use/If unknow	en, give duration) from/t	
Death: Death: Deathity or Permanent Damage	test estimate) e1 09/01/2009	03/21/20	Stopped or Dose Reduced?
Life-throatening Gongenital Anomaly/Birth Defect	#1 03/01/2002	00/88/80	Apply
Hospitalization - Initial or prolonged Other Serious (Important Medical Events)	#2	to the distinction	#2 Yes No Deen't
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	4. Diagnosis or Reason f	or use (moxemon)	Event Reappeared After     Reintroduction?
Date of fivent (mm/dd/yyyy)     4. Date of this Report (mm/dd/yyyy)	W1		at Tyes T No T Opesn't
09/01/2009 03/28/2011	#2		Apply
5. Describe Event, Problem or Product Use Error	6. Lot #	7. Expiration Date	#2 Yes No Decent
Rash around your face and started to get worse Constant constipation Lungs started	#1	41.	9. NDC # or Unique ID
hurting-pain increased in 2009/2010- The	A2	42	
way the product is designed you	E. SUSPECT MED	ICAL DEVICE	
inadvertently swallow the ejuice which	1. Brand Name		
causes burning in throat When you charge the batteries and take them off the charger	2. Common Device Name	e	
it looks like battery acid forming. The only	3. Manufacturer Name, C	ity and State	
thing you can do is throw the batteries			
away. Replacement parts aren't any good.	4. Model #	Lot#	5. Operator of Device
		Eur F	Health Professional
	Catalog #	Expiration D	ate (mm/dd/yyyy) Lay UsedPatient
RECEIVED	Serial #	Other #	Other
	6. If Implanted, Give Date	e (mm/dd/yyyy) 7.	If Explanted, Give Date (mm/dd/yyyy)
MAR 5.9 2011	II. Is this a Single-use De	urice that was Beerner	assed and Reused on a Patient?
	Yes No	VICE MAN PROPRESE	resid and reduced on a restant
MEDWATCH CTU More	9. If Yes to Item No. 8, Er	nter Name and Addres	s of Reprocessor
6. Relevant Tests/Laboratory Data, Including Dates			
-last chest xray was 3-4 months ago which show spot in left lung which has been there			
	F. OTHER (CONC	OMITANT) MEDIC	CAL PRODUCTS
	Product names and then	OTHER DESIGNATION ASSESSMENT OF THE PERSON NAMED IN	
More			[
<ol> <li>Other Relevant History, Including Preexisting Medical Conditions (e.g., allorgies, race, prignancy, smoking and alcohol use, liverikidney problems, etc.)</li> </ol>	G. REPORTER (Se	na aantidantialitu	More More
Diagnosed with emphysema back in 1996	(b) (6)	ee connaemiamy	section on backy
Diagnosed with days John Dave in 1990	(b) (6)		
	Phone #	10	mail
More	Phone # (k	0) (6)	mail
C. PRODUCT AVAILABILITY	2. Health Professional?		4. Also Reported to:
Product Available for Evaluation? (Do not send product to FDA)	Ves No		Manufacturer
Yes No Beturned to Manufacturer on:	<ol><li>If you do NOT want yo to the manufacturer, p</li></ol>		User Facility  Distributor/Importer

U.S. Department of Health and Human Services

The FDA Safety Information and

Form Approved: OMB No. 0910-0291, Expires: 10/31/08

See OMB state JNTARY reporting of **MEDWATCH** FDA USE ONLY adverse events, product problems and  $\mathcal{DOR}$  Triage unit product use errors Internet Submission - Page 1 Adverse Event Reporting Program A. PATIENT INFORMATION D. SUSPECT PRODUCT(S) Weight 1. Patient Identifier | 2. Age at Time of Event, or 3. Sex Name, Strength, Manufacturer (from product tabet) Smokefree Smoke Free Date of Birth: 185 Female (b) \*Electronic ✓ Male B. ADVERSE EVENT, PRODUCT PROB Dose or Amount Frequency Route as needed unkown Inhal Product Problem (e.g., defects/mailunctions) Product Use Error Problem with Different Manufacturer of Same Medicine Outcomes Attributed to Adverse Event Event Absted After Use (Check all that apply) Dates of Use(If unknown, give duration) from/to (or best estimate) Stopped or Dose Reduced? Disability or Permanent Damage Death: #1 Yes No Doesn't #1 05/09/2011 (mm/dd/yyyy) Congenital Anomaly/Birth Detect Life-threatening Ocesn't #2 Yes No Other Serious (Important Medical Events) Hospitalization - initial or prolonged Apply 4. Diagnosis or Reason for Use (Indication) Required Intervention to Prevent Permanent Impairment/Damage (Devices) 8. Event Reappeared After quit smoking ade Reintroduction? 4. Date of this Report (mm/dd/yyyy) 3. Date of Event (mm/dd/yvvy) #1 Yes No 05/12/2011 05/11/2011 #2 Doesn' Apply 6 Lot# 7 Expiration Date 5. Describe Event, Problem or Product Use Error #2 Yes No none the e-cigarette product is leaking large 9. NDC # or Unique ID amounts of nicotine. i took a few puffs and **#**2 none it leaked all in my mouth causing an adverse E. SUSPECT MEDICAL DEVICE reaction including, redness and swelling of 1 Brand Name lips, and red dots on hands. Smoke Free 2. Common Device Name Gold Edition 3. Manufacturer Name, City and State www.smokefreeonline.com Smoke free 4. Model # RECEIVED not mentioned Health Professiona Expiration Date (mm/dd/yyyy) Catalog # Lay User/Patient Other. Other # Serial # MAY 13 2011 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yvyy) MEDWATCH CTU 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes Z No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor More 6 Relevant Tests/Laboratory Data, Including Dates F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) More More Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) G. REPORTER (See confidentiality section on back) 1. Name and Address Caucasian male, smoker (b) (6) F-mail More (b) (d) Health Professional? Also Reported to: 3 Occupation C. PRODUCT AVAILABILITY Consumer/Non-Health Yes V No Manufacturer Product Available for Evaluation? (Do not send product to FDA) User Facility 5. If you do NOT want your identity disclosed Yes No Returned to Manufacturer on: to the manufacturer, place an "X" in this box Distributor/Importer

FORM FDA 3500 (8/05)

a restriction of the

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

(mm/dd/yyyy)

U.S. Department of Health and Human Services

adverse events, product problems and product use errors

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

# **MEDWATCH**

MEDWATO	adverse events, p	product problems and		DA USE ONLY
	produc	t use errors /	Triage unit 45	63/5
The FDA Safety Information and Adverse Event Reporting Programmer	/ incerner submissi	on - Page 1 DQ	rs - · ·	errical lancer florest moves and come to a series of the control of the decimal series of the control of the co
A. PATIENT INFORMATION		D. SUSPECT PRO		
1. Patient Identifier   2. Age at Time of E	Event, or 3. Sex 4. Weight	7	ufacturer (from product label)	
(b) (6) Date of Birth: (b) (6	Female 120 lb	Inhale		
In confidence 24 Years	s Maie kg	Electronic		
B. ADVERSE EVENT, PRODU	CT PROBLEM OR ERROR	*2cigarette 2. Dose or Amount	Frequency	Route
Check all that apply:		<b>1 1 1 1 1 1 1 1 1 1</b>		- Noute
1. Adverse Event Product P	robiem (e.g., delects/mallunctions)			
2. Outcomes Attributed to Adverse Even	vith Different Manufacturer of Same Medicine	#2		
(Check all that apply)	ot.	3. Dates of Use /// unknow	wn, give duration) from/to (or	5. Event Abated After Use
Death: (mm/dd/yyyy)	Disability or Permanant Damage	best estimate)		Stopped or Dose Reduced?
Life-threatening	Congenital Anomaly/Birth Delect	#1 06/01/2011	06/10/2011	#1 Yes No Doesn't
Hospitalization - initial or prolonged	Other Serious (Important Medical Events)	#2		#2 Yes No Doesn't
Bequired Intervention to Prevent Per	manent impairment/Damage (Devices)	4. Diagnosis or Reason f Help quit amo	or Use (Indication)	8. Event Reappeared After
3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)	#1		Reintroduction?
06/01/2011	06/10/2011	#2		#1 Yes No Doesn't
5. Describe Event, Problem or Product U	se Error	5. Lot #	7. Expiration Date	#2 Vas No Doesn't
I quit smoking cigare	ettes about a week ago.	#1	#1	— Apply
I decided to make it	easier on myself I	#2	#2	9. NDC # or Unique ID
only been a week and	onic cigarette it has	E. SUSPECT MED	1	
problems with my heal	lth. Im having nose	1. Brand Name		
bleeds and coughing	just as much as I was	Inhale 2. Common Device Name		
	d menthol cigarettes I	Electronic ciga		
smoked for 15yrs! I w	was a heavy smoker a day so I thought it	3. Manufacturer Name, Ci	ity and State	
was just my lungs try	ying to repair but I			
have noticed I cough	more after I use the e	4. Model #	Lot #	5 Operator of Device
cigarette and it leav	ves a strange chemical	***************************************		Health Professional
nose bleeds im not ev	my throat. As for the are how to explain the	Catalog #	Expiration Date (mi	n/od/yyyy) Lay User/Patient
reason im getting the	em but I never really	Serial #	Other #	Other.
had problems with				
		6. If Implanted, Give Date	(mm/dd/yyyy) 7. If Exp	lanted, Give Date (mm/od/yyyy)
	1	8 is this a Single-use Day	rice that was procedured	
	Ī	Yes No	HFT.	HIVHI')
	More	9. If Yes to Item No. 8, Ent	er Name and Address of Re	processor
5 Relevant Tests/Laboratory Data, Includi	Later Association		JUN	13 2011
			3014	-0 6011
			8 ATT 1 A / 4	TOLLOT
			MEDWA	ATCH CTU
		F. OTHER (CONCO	MITANT) MEDICAL PI	RODUCTS
			py dates (exclude treatment o	
	1			
- A COUNTY OF THE PROPERTY OF	Nore			
Other Relevant History, including Preex race, pregnancy, smoking and alcohol use,	isting Medical Conditions (e.g., allergies, liver/kidney problems, etc.)	C REPORTED (C		More
	and the second second	G. REPORTER (See	e confidentiality secti	on on back)
	ļ	Walke allo Address		(b) (6
				14,14
	****			
	More	Phone #	E-mail	A. A.
C. PRODUCT AVAILABILITY	- Indiana	2. Health Professional? 3.	Occupation	4. Also Reported to:
roduct Available for Evaluation? (Do not s	end product to FDA)	Yes No		Manulacturer
Z Yes No Returned to M	Aanufacturer on:	5. If you do NOT want your	identity disclosed	User Facility
	(mm/dd/yyyy)	to the manufacturer, place	e an "X" in this box:	Oistributor/importer

FORM FDA 3500 (8/05)

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

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

Internet Submission - Page 2

## B5. Describe event or problem continued

nose bleeds in my past I have had about 5since I have started using the e cigarette just 1WEEK ago!

Mail to: MEDWATCH

ATCH or FAX to:

1-800-FDA-0178

5600 Fishers Lane Rockville, MD 20852-9787

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

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U.S. Department of Health and Human Services

# MEDWATCH

The FDA Safety Information and

OLUNTARY reporting of

adverse events, product problems and product use errors

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

A CONTRACTOR OF STREET

DA USE ONLY

Triage unit

Internet Submission - Page 1 CDER **Adverse Event Reporting Program** A. PATIENT INFORMATION D. SUSPECT PRODUCT(S) 1. Patient Identifier 2. Age at Time of Event, or Name, Strength, Manufacturer (from product label) 170 electronic puresmoker.com Female (b) cidarette lithium batteries / Maic cr123a 3.0v titanium B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR innovations Dose or Amount Frequency Route Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine Outcomes Attributed to Adverse Event (Check all that apply) Dates of Use (If unknown, give duration) from/to (or best estimate) Event Abated After Use Death: Stopped or Dose Reduced? Disability or Permanent Damage (mm/dd/yyyy) #1 06/26/2011 #1 Yes No Doesn' Apply 06/26/2011 Life-Ihreatening Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Events) #2 Yes No Doesn't Diagnosis or Reason for Use (Indication) Required Intervention to Prevent Permanent Impairment/Damage (Devices) smoking cessation 8 Event Reappeared After 3. Date of Event (mm/dd/yyyy) Date of this Report (mm/dd/yyyy) Reintroduction? #1 Yes No Doesn' 06/27/2011 06/27/2011 #2 #2 Yes No Doesn' Apply 5. Describe Event, Problem or Product Use Error 5. Lot # #1 unk Pt stated was smoking a lithium powered 9. NDC # or Unique ID e-cigarette while he was driving and it #2 unk none exploded in his mouth, causing 2nd degree burns to his face, mouth and injury to his E. SUSPECT MEDICAL DEVICE left eye. He was treated in our ER and 1. Brand Name titanium innovations lithium batteries and transferred to a burn center in Bakersfield, 2 Common Device Name e cigarette 3. Manufacturer Name, City and State purchased online RECEIVED Lot # 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) JUN 28 2011 Lay User/Patient Other Serial # MEDWATCH CTU 6. If Implanted, Give Date (mm/dd/yyyy) 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 More 6 Relevant Tests/Laboratory Data, including Dates F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) More Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) More G. REPORTER (See confidentiality section on back) 38 year old white male, no meds, no significant PMH, no allergies, smokes approx. 5 cigarettes per day, no alcohol E-mail More (b)(6)C. PRODUCT AVAILABILITY 2. Health Professional? 3. Occupation 4. Also Reported to: Product Available for Evaluation? (Do not send product to FDA) Yes No Manufacturer If you do NOT want your identity disclosed Yes No Returned to Manufacturer on \_ User Facility (mm/dd/yyyy) to the manufacturer, place an "X" in this box: Distributor/importer

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# MEDWATCH

The FDA Safety Information and

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

Internet Submission - Page 1

Form Approved.	OMB	No.	0910-0	291,	Expires:	10/31/	Qŧ
					arment a		

FDA USE ONLY Triage unil sequence #

ldverse Event R	eporting Program					<u> </u>			
A. PATIENT INF	ORMATION				PECT PRODU				
AM . A . 201901	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight 183 ib		strength, Menulu eenSmok		uct label)		y Testina International
(b) · · ·	(b) (6)	Female Mate	or to kg	91 61	CETIONICK	G 01		Gra	<u>-1</u>
In confidence	53 Yea VENT, PRODUCT PRO			#2					
Check ell thet apply:					or Amount		equency		Route    Continue   Co
Adverse Event	Product Problem (e.g	. delecis/malfunction	ns)	#1 Cil.			CIMUS		tinhalation)
	rrar Problem with Differer			•2					
	ed to Adverse Event							r= =	
(Check all that appl)				3. Dates of bost of	ol Use(If unknown timata)	give durution) in Weeks	om/to (er		Abated After Use od or Dose Reduced?
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Life-threatening		ongenitel Anomaly/Bi		#2		••		T.	os No Doosn'i
= '		ther Serious (Importa			els or Reason for	· Use (Indication)		<b></b>	— Афру
· CED .	rontion to Provent Permanent Im				r real ciga:				Reappeared After aduction?
3. Date of Event (mm	(dd/yyyy) 4. Detr	o of this Report (mr 08/02/2011	n/Gd/yyyy)	#2				n 🗆 v	es No Doesn't
C Describe Front S	roblem or Product Uso Error	00/02/2011		#2 6. Lpt #		7. Expiration D		- 100	
· · · · · ·	and e-cigarette	o company	uses	A330	008	05/20/20			OS LINO LIApply
	glychol in their			<u> </u>		P1		1	or Unique ID
using the	product I have h	nad a produ	uctive	12		12		A330	18
	utum greenish ye				PECT MEDIC	AL DEVICE	1, 21		
	er respiratory in and my allergie			r. Brand	ENSMOKE				
	he product cause			2. Comm	CARETTE				
	r hours after.		-	3. Manufi	cturer Name, Cit	y and State			
				Chi					
				4. Model	<u> </u>	Lot #	-		5. Operator of Device
	חדר		ח	- mouet	-	V3 3 0 0 8			Health Professional
	REC		U	Catolo	, •		on Date (m		Lay User/Patient
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	AUG	03 2011		Serial	•	Other #			
				6. If impli	ented, Givo Date (	(mm/dd/yyyy)	7. H Exp	lanted, Gi	ve Date (mm/dd/yyyy)
	MEDW	ATCH C	ידט ו	2 2 2 2	- Ole ata O	las Nacional E	1	- 45	d = - Ballana
	MEDAA			8. te this	a Single-use Devi s	we mei was Rep	recessed (	ına Heuse	u on a Paliënt?
					o Rom No. 8, Ent	er Name and Ad	dress of Ro	processo	t
			<del></del>						
6. Relovant Tests/La	boratory Date, including Dates	1							
				F. OT	IER (CONCO	MITANT) ME	DICALE	RODUC	CTS
				Product	names and there	py dates (exclud			
				None	Stopped	usage			
7. Other Relevant Hi	story, including Preexisting Me	edical Conditions (c	g., allergies,		OOTED 10				
	moking and alcohol use, livei/hid .dism Hypomagne:				PORTER (Se	e contid <b>e</b> nti.	nity seci	TON ON I	
Hyperaldos	teronism								(b) (6)
	on/Hypotension		without		4.5%				
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GERD Stro	,			Phone II	(b) (6)		E-mail		
C. PRODUCT A	VAU ARIETY			, <del></del>		3 Occupation	<u> </u>	].	Also Reported to:
	r Evaluation? (Do not sond proc	duct to FDA)		[Z] Ye	No	Othor Health	Profes	u tona l	Munulacturer
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(mm/dd/yyyy)

U.S. Department of Health and Human Ser

The FDA Safety Information and

**Adverse Event Reporting Program** A. PATIENT INFORMATION

# DORS

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

Internet Submission - Pa

For	m Approved:	OMB N	0.09104	0291.	Expires:	10/31/0
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FDA USE ONLY

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	e or Amount		Frequency		Route	
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	pels or Reason for	Une (Indical	on)	<u> </u>	res No	Apply
#1				8. Event Reintr	Reappeared oduction?	After
#2				** 🗆 \	es No	Doesn't Apply
6. Lot#		7. Expiration	Date	#2 🗆 Y	es No	Doesn't Apply
*1	···	<u>#1</u>		9. NDC #	or Unique ID	
#2		#2				
1. Brand	SPECT MEDIC	AL DEVID	E			
<b></b>	on Device Name	· · · · · · · · · · · · · · · · · · ·				
<u> </u>						
3. Marium	scturer Name, City	and State				
4. Model	<u> </u>	1			T	
4. 11004	•	Loi			5. Operator	
Catalo	9 *	Explic	tion Date (mn	r/dd/yyyy)		Professional er/Patient
Serial (	,	Other			Other	
6 If Imple	Inted, Give Date (		7 46-1		-	
Ĺ			ľ		e Date (mm/d	
8. is this :	s No	o that was R	eprocessed a	nd Reusec	on a Patient	7
	o item No. 8, Ente	Name and A	ddress of Re	processor	<del></del>	
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2. Health F	rofessional? (3. (	Occupation				(b) (6)
☑ Yes	□ № P	<b>-</b> ' 1	nacis		Also Reports  Manufactu	•
	NOT want your k	dentity disclo	eed .		User Facil	1
	anufacturer, place				Distributor	/Importer

(b)	it identifier	2. Age at Time of Ever	it, or	3. Sex		4. Weight	
1 7-1		Date of Birth: (b) (6)		Fen	i i	18 or	, lb
	nfidence	8 Mon VENT, PRODUCT	PROF	L MAI			_ kg
	I that apply:			JULIN OIL			
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<b>—</b>	roduct Use E		Differen	t Menufactu	wer of Sa	me Medicin	
	mes Attribut k all that appl	led to Adverse Event					
	eath:		Die	ability or Per	manent i	Damage	
1 1	ite-threatening	(mm/dd/yyyy)	Cor	ngenital Ano	maty/Birti	n Defect	
	ospitalization	- initial or prolonged	-			Medical Eve	mis)
	equired Interv	rention to Prevent Permai	neni imp	Birment/Den	rage (De	rices)	
	8/14/201			of this Rep		ddiyyyy)	
-		obiem or Product Use t		09/27/20	11	<u></u>	
		developed wh		nneara	d to	bo a	
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afte	nmic r r retu	ight shoulde rn to the US	r sh: . bu	rug. L rean	This Dear	taded	
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7. Other R	Relevant Hist	ory, including Preexisting oking and alcohol use, live	ng <b>Me</b> dic	el Conditio	ns (e.g.,	allergies,	ㅓ
	-g		on/ rous ray	problems, e	nc.)		
0.000	DUCE						
		AILABILITY Evaluation? (Do not send	ometica	In FD≜1			
✓ Yes	_	_					
	-	Returned to Man	wacturer	on:	(mm/dd	)))))	
FORM F	DA 3500	(8/05) Submissio	on of a	report doe		onstitute an	adı



For VOLUNTARY reporting by health professionals of adverse events and product problems Internet Submission - Page 2

# 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

discontinuing its use indoors, our daughter's spasm has not recurred. symptoms of nicotine toxicity to my knowledge.

Mall to: MEDWATCH or FAX to: 5600 Fishers Lane Rockville, MD 20852-9787 1-800-FDA-0178

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



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

HB	FDA Comments							· <b>y</b> - ·	1		
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Mail t	: MEDWATCH 6600 Fishers Lane	or FAX to: 1-800-FDA-0178		<del></del>							

6600 Fishers Lane Rockville, MD 20852-9787

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

# MEDWATCH

For VOLUNTARY reporting of adverse events, product problems and

Form	Approved:	OMB	No.	0910	-0291	, Expires	: 10/31/08
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Distributor/Importer

	Information and			use errors	Triage uni sequence	US-FDA-	194500		
A. PATIENT IN		3. Sex	4. Weight 185 lb	D. SUSPECT PRO 1. Name, Strength, Man Metro monthol #1 electronic sig	ufacturer (from		N:	lcotek	
In confidence	53 Yea	Male	or kg	#2					
Check all that apply:	EVENT, PRODUCT PR	ORLEM OH EH	HOH	2 Dose or Amount		Frequency		Route	
1 Adverse Ever		e.g., defects/mailunct	NS2-94	#1		-			
Outcomes Attribu (Check all that app     Death:	(mm/dd/yyyy)	Disability or Permane		3 Dates of Use(If unknot best estimate) et 10/13/2011		n) from/to (or 14/2011	Stoppe	Abated After	
<u> </u>		Other Serious (Impor		#2	***		#2  Y	es No	Doesn't Apply
	vention to Prevent Permanent	Impairment/Damage ( ate of this Report (n		4. Diagnosis or Reason As a substit				Reappeared oduction?	After
10/14/201	100170750	10/17/2011	10.7.582445	#2			#1 Y	es No	Ocean't Apply
5. Describe Event, P	roblem or Product Use Error			6. Lot #	7. Expiratio	n Date	#2 Y	as No	Doesn't Apply
	day using a Nic			#1	#1		9. NDC #	or Unique II	
	cigarette in mal cigarettes.			#2	#2				
I noticed and felt l	that my throat ike they might the vapor. I	and chest possibly h	ached nave been	E. SUSPECT MED	DICAL DEVI	CE			
since with	shortness of l	oreath and		2. Common Device Nam electronic ci	garette				
	breathing. The use. I have to			3 Manufacturer Name, Nicotek, LL CO 80033	City and State C 4860	Ward Roa	ad, Who	eat Rid	ge,
				4. Model #	Lat #			5. Operator	of Device
				Metro menthol 1 Catalog#		ration Date (m	m/dd/yyyy)	=	Professional senPatient
				Serial #	Othe	r #		Consum	er
				6. If Implanted, Give Dat	te (mm/dd/yyyy)	7. If Exp	slanted, Giv	e Date (mm/	dd/yyyy)
				8. Is this a Single-use D	0.000	Intra-option	Story Co. S. A.	i on a Patien	t?
				9. If Yes to Item No. 8, E	nter Name and	Address of R	aprocessor		
None yet.	boratory Data, Including Date	CS .							
				F. OTHER (CONC Product names and the				TS	
Have smoke	story, Including Preexisting I moking and alcohol use, Iverib ed Salem menthol years but have	l cigarette		G. REPORTER (S	See confider	ntiality sec	tion on b		(b) (6)
				Phone #		E-mail			(b) (6
C. PRODUCT A	VAILABILITY	2 12 12 15 15		2. Health Professional?	3. Occupation	1	4.	Also Repor	
Product Available for	r Evaluation? (Do not send pro	oduct to FDA)		Yes No	Donastes 70 Okto	est Bealth pro	fereional	Manufac	turer
Yes 🗌 No	Returned to Manufac		m/dd/yyyy)	<ol> <li>If you do NOT want you to the manufacturer, p</li> </ol>				User Fa	cility tor/importer

(mm/dd/yyyy)

Diagnosis for Use	Start Date	End Date	Duration	Unit

# FDA Comments:

USFDAMWVOLUNTARY 194500 B181 20111017.xml Route To: AERS : Electronic Route To: DQRS : : Paper Route To: CDRH : : Paper I need a copy for Tobacco Center	

Mail to: MEDWATCH

or FAX to:

1-800-FDA-0178

5600 Fishers Lane Rockville, MD 20852-9787

Return to Form



3. Sex

Adverse Event Product Problem (e.g., delects/melfunctions)

Product Use Error Problem with Different Manufacturer of Same Medicine

Fomaio

Disability or Permanent Damage

Congenital Anomaly/Birth Defect
Other Serious (Important Medical Event

4. Date of this Report (mm/dd/yyyy)

01/22/2012

Male Male

DORS

CORH

U.S. Department of Health and Human Services

The FDA Safety Information and

Check all that apply:

1. Adverse Event

Death:

Life-threatening

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

01/21/2012

Adverse Event Reporting Program

A. PATIENT INFORMATION

Outcomes Attributed to Adverse Event (Chock all that apply)

Hospitalization - initial or prolonged

5. Describe Event, Problem or Product Use Error

6. Relevant Yesta/Laboratory Data, Including Dates

2. Age at Time of Event, or

ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Required Intervention to Prevent Permanent Impairment/Damage (Devices)

I was using an electronic cigarette when i

RECEIVED

JAN 23 2012

MEDWATCH CTU

 Other Refevant History, Including Proexisting Medical Conditions (e.g., allorgios, race, programcy, smoking and alcohol uso, bivor/kidnoy problems, etc.)

Returned to Manufacturer on:

(mmAdd/yyyy)

started having chest pain then an extremelly rapid heartbeat. I called an ambulance and was transported to the hospital. The cigarette brand was N-Joy.

(b) (6) 27 Yea

(mm/dd/yyyy)

MEDWATCH

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

Internot Submission - Page 1

4. Weight 115 Form Approved: OMB No. 0910-0291, Expires: 10/31/08 See OMB statement on reverse.

FDA USE ONLY

Triage unit US-FDA-200017

3. Dates of Use/If unknown, give duration) from/to (or best estimate)  \$1			
### Stopped or Amount   Frequency   Route			
### Cigarette   Ti / d   NJOY   ###   ###   NJOY   ###	Njoy electron	nic ,	
Dose of Amount		11/d	1400}
3. Detes of Use (ff unknown, give duration) from/to (or best estimate)  3. Detes of Use (ff unknown, give duration) from/to (or best estimate)  3. Detes of Use (ff unknown, give duration) from/to (or best estimate)  3. Detes of Use (indication)  4. Note of Use (indication)  4. Note of Use (indication)  5. Event Responsed And indication?  5. Detes of Use (indication)  5. Detes of Use (indication)  5. Detes of Use (indication)  6. Detes of Use (indication)  6. Detes of Use indication?  6. Detes of Use Indication?  7	#2		
3. Dates of Useff Immrown, give duration) from/to (or best estimate)  \$1. 01/19/2012 01/21/2012  \$2	2. Dose or Amount	t Frequency	Route
Substance of Use (if unknown, give duration) from/to (or best estemate)  \$1 \ 01/19/2012 \ 01/21/2012  \$2 \ -	#1		
Substance of Use (if unknown, give duration) from/to (or best estemate)  \$1 \ 01/19/2012 \ 01/21/2012  \$2 \ -	42		
Stopped or Dose Reduent   1   1   1   1   1   1   1   1   1			
## O1/19/2012 01/21/2012 ## OYOS NO		known, give duration) from/to (or	
### Professional?  ###################################	-	03/21/2012	
8. Lot # Professional Profession   B. Event Reappoored And Reintroduction?   St. Lot #   Professional Profess			-
8. Lot 9 91		on the time Hadrana	
### Product names and therapy dates (exclude treatment of event)  ### Product names and therapy dates (exclude treatment of event)  ### Product names and therapy dates (exclude treatment of event)  ### Product names and therapy dates (exclude treatment of event)  #### Product names and Address (b) (6)  ###################################	_	en ros usa (indicătion)	6. Event Reappoored Afte
8. Lot #   7. Expiration Date   #2   Yes   No     91   10   10   10   10   10   10	<u></u>		-
## ## ## ## ## ## ## ## ## ## ## ## ##			
# SUSPECT MEDICAL DEVICE  1. Brace Name 2. Comman Device Name 2. Comman Device Name 2. Comman Device Name 2. Comman Device Name 2. Comman Device Name 3. Manufacturer Name, City and State 3. Manufacturer Name, City and State 3. Scottsdale.arizona 4. Model # Let # 5 Operator of C Health Proi  Catalog # Expiration Date (mm/dd/yyyy)  7. If Explanted, Citye Date (mm/dd/yyyy)  8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?  Yes No  8. If Yes to from 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)  Name and Address  (b) (6)  Phone # E-mail  (b) (6)  4. Also Reported to the second of the section of the sec	6. Lot #	7. Expiration Date	#2 Yes \ No
E. SUSPECT MEDICAL DEVICE  1. Brand Neme 2. Comman Device Name electronic cigarette 3. Manufacturer Neme, City and State SCOTTSCAILE. AT 1 ZONA  4. Model # Let # 5 Operator of Cigarette Catalog # Expiration Date (mm/dd/yyyy) Sertal # Other # Other # Other.  6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Cive 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 Nom 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) Name and Address (b) (6)  Phone # E-mail (b) (6)  Ven [7] No 4. Also Reported to See [8]  Phone # E-mail (b) (6)  A last Reported to See [8]	na et		9. NDC # or Unique ID
E. SUSPECT MEDICAL DEVICE  1. Brand Name 2. Comman Davice Name electronic digarette 3. Manufacturer Name, City and Siple Scottsdale.arizona  4. Model # Let # 5 Operator of City and Siple Catalog # Expiration Date (mm/dd/yyyy)  Sertal # Other # Other # Other  8. Il 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 Nom 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)  Chestiff Professional?  1. Also Reported to City and City a	#2	#2	- 1 · · · ·
1. Brand Neme 2. Comman Davice Name electronic Cigarette 3. Manufacturer Nama, City and State SCOTTSCALE. ATIZONA 4. Model #	E. SUSPECT M	EDICAL DEVICE	
2. Common Device Name electronic Cigarette 3. Manufacturer Name, City and Bipte SCOTTSCIALE. ATIZONA 4. Model # Lot # 5 Operator of Catalog # Expiration Date (mm/dd/yyyy)  Serial # Other # Other # Other.  6. If implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy)  8. Is this a Singlo-use Device that was Reprocessed and Reused on a Patient?  Yes No 9. If Yes to from No. 8, Enter Name and Address of Reprocessor  F. OTHER (CONCOMITANT) MEDICAL PRODUCTS  Product names and therapy dates (axclude treatment of event)  G. REPORTER (See confidentiality section on back)  Name and Address  (b) (6)  Phone # E-mail  (b) (6)  4. Also Reported 1	1. Brand Name	1	
Scottsdale.arizona  Model # Lot # 5 Operator of Catalog # Expiration Data (mm/dd/yyyy)		large	
Scottsdale . arizona  A. Model # Let # 5 Operator of E   Health Professional?   Health Professional?   House Professional?   Lay Usur/P   Catalog # Expiration Date (mm/dd/yyyy)   T. If Explanted, Give Date (mm/dd/yyyy)   T. If Explanted, Gi	<del></del>	<del></del>	
Catalog # Expiration Date (mm/dd/yyyy)  Serial # Other # Other # Other # Other.  B. 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?  Yos No  8. If Yes to Rem No. 8, Enter Name and Address of Reprocessor  F. OTHER (CONCOMITANT) MEDICAL PRODUCTS  Product names and therapy dates (axclude treatment of event)  G. REPORTER (See confidentiality section on back)  Name and Address  (b) (6)  Phone # E-mail  Let # Department of the processor of the	3. Manufacturer Nam	ic, City and State	
Catalog # Expiration Date (mm/dd/yyyy)  Serial # Other # Other # Other # Other.  8. Il 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?  Yos No  9. If Yes to flem No. 8, Enter Name and Address of Reprocessor  F. OTHER (CONCOMITANT) MEDICAL PRODUCTS  Product names and therapy dates (axclude treatment of event)  G. REPORTER (See confidentiality section on back)  Name and Address  (b) (6)  Phone # E-mail  (b) (6)  4. Also Reported to the service of the control of the con		UIIQ	
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Seriel # Cither # Other # Other.  Seriel # Other # Other # Other.  B. Il Implanted, Give Date (mm/dd/yyyy)   7. If Explanted, Give Date (mm/dd/yyyy)   7. If			Health Prof
Serial e Other # Other # Other.  6. If implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/y  7. If Explanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/y  8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?    Yes	Catalog #	Expiration Date	
6. It implanted, Give Date (mm/dd/yyyy) 7. It Explanted, Give Date (mm/dd/y) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?    Yos	Seriel A	Office =	
B. Is this a Single-use Device that was Reprocessed and Reused on a Patient?  Yes No  B. If Yes to flom No. 8, Enter Name and Address of Reprocessor  F. OTHER (CONCOMITANT) MEDICAL PRODUCTS  Product names and therapy dates (axclude treatment of event)  G. REPORTER (See confidentiality section on back)  Name and Address  (b) (6)  Phone 8  E-mail  (b) (6)  4. Also Reported 1		SHORT F	
B. Is this a Single-use Device that was Reprocessed and Reused on a Patient?  Yes No  B. If Yes to flom No. 8, Enter Name and Address of Reprocessor  F. OTHER (CONCOMITANT) MEDICAL PRODUCTS  Product names and therapy dates (axclude treatment of event)  G. REPORTER (See confidentiality section on back)  Name and Address  (b) (6)  Choice S  Lendth Professional?  J. Occupation  4. Also Reported 1	6. Il Implantas, Give I	Date (mm/dd/yyyy) 7. If E	splanted, Give Date (mm/dd/y)
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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS  Product names and therapy dates (axclude treatment of event)  G. REPORTER (See confidentiality section on back)  Name and Address (b) (6)  Check the section of			d and Reused on a Patient?
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G. REPORTER (See confidentiality section on back)  Name and Address (b) (6)  Chone s  Health Professional?  Also Reported to the section of t		, Our and mountes of	हुन्न च क्ष्म् य क्षित
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L Yes V No Manufacture	(b) (6)	E-mail	
	(b) (6)  Thore s	E-mail	
to the manufacturer, place an "X" in this box: Distributor/im	hone s  Health Prolessions Yes No	E-mail	o) (6) <u></u>

□ №

☑ Yes

C. PRODUCT AVAILABILITY

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

U.S. Department of Health and Human Services



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

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

	FDA USE ONLY	
riage unit	US-FDA-199894	 

The FDA Safety Informatio Adverse Event Reporting F	n and	Internet S	produc - Submission	Page 1	sequence #	er of the state of the day of the process of the state of
A. PATIENT INFORMATION				D. SUSPECT PR	ADUCT/C)	
1. Patient Intentities   2. Age at Tim	ne of Event, or	3. Sex	4. Weight		inufacturer (from product label	
(b) (6) Date of Bi	as dan application woman.	Female	182 lb	Atomic Cinn	acide 24 mg. nicot	ine Tasty Vapor US
In confidence 51 Y	ea	Male	orkg			tine Tasty Vapor US
B. ADVERSE EVENT, PR Check all that apply:	ODUCT PRO	BLEM OR ERF	ROR	2. Dose or Amount	Frequency	For (\$\darks) = \$\darks\tanks
F 23	tuet Deablem /s.	g., defects/malfuncti		#1		
Product Use Error Prot						The property of the control of the c
2. Outcomes Attributed to Adverse	and the second s			#2		Market in the particular programmer and programmer
(Check all that apply)	green			3. Dates of Use(If unkil best estimate)	nown, give duration) from/to (or	
Death: (mm/od/yyyy	7)	isability or Pormaner	•	#1 12/26/2011	- 01/07/2012	Stopped or Dose Reduced?
Life-threatening	part of the part o	ongenital Anomaly/E				Apply
Hospitalization - initial or profe		ther Serious (Import		#2 4. Diagnosis or Reaso	n for Use (Indication)	#2 Yes No Doesn't
3. Date of Event (mm/dd/yyyy)	or the second control of the second control	and the second of the second o		smoking ces		8 Event Reappeared After Reintroduction?
12/26/2011	4. Dat	e of this Report (m. 01/19/2012	m/dd/yyyy)	#2		#1 Yes No Dousn't
5. Describe Event, Problem or Proc	duct Use Error		***************************************	6. Lat #	7. Expiration Date	Appy
Tried to use a Mi	stic bran	nd full-fl	avored	#1	Manual sec	M2 Lifes No Li Apply
e-cigarette in or	der to st	op smokin	g	#2	#1	9. NDC # or Unique ID
tobacco cigarette so I ordered a Bl	s. Did no	ot like th	e taste,	E. SUSPECT ME	DIOAL DEVICE	
the vanilla cartr	u cig sta idges. I	did not 1	ike the	1. Brapd Name 14 10 56 Sta		
Blu e-cig either,	so I ord	dered a Ha	lo G6	era sini neriman manimum integrati ayar ayar ayar ayar ayar ayar ayar aya		
starter kit. With must add smoke ju.	this typ	e of e-ci	g, you	2. Common Device Na E-Cigarette	me	***
order to keep the	unit ope	erational.	zer, in The	Manufacturer Name, Halo Comp		erlinenskalad (generinensstatenskaladerinenska
flavors that Halo	offered	were terr	ible,	11.010 00111	parry	9-1
but I tried one ca	alled Pri	me 15, wh	ich is	4. Model #	Lot #	5 Operator of Device
suppose to be the flavor tasted like	ir best s e peanut	butter wh	ich I	G6		Health Professional
disliked very much	h. I orde	red some	smoke	Catalog #	Expiration Date (n	nm/dd/yyyy)
juice from a compa	any in Ca	lifornia,	called	Serial #	Other#	Other:
Tasty Vapors. The	se are ma	de				
				6. If Implanted, Give Da	ite (mm/dd/yyyy) 7. If Ex	planted. Give Date (mm/dd/yyyy)
			construction of the constr	8. Is this a Single-use [	Device that was Reprocessed	and Reused on a Patient?
				Yes No	gerkyttigkelengis insegenses dijts over eitte statistisch vor delengingsbesonstittigtsbesonstittigtsbesonstitt	materian sprome supplying distribution is a second material and the supplying and the spring of the supplying a
				9. If Yes to Item No. 8, I	Enter Name and Address of R	eprocessor
3. Relevant Tests/Laboratory Data, i	Including Dates	te e the direction and management and filled to the partie of the department of the second se	Makada kalan da kalan sa da karangan yang pengungan pengungan kalangan pengungan pengungan pengungan pengungan			
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		. 00 0040		E ATUEN (AAV		
	JAN	1 20 2012	Ī		COMITANT) MEDICAL I	
					The state of the s	or crem,
	VIEDW	'ATCH (	CTU			and the second s
·						
Other Relevant History, Including race, pregnancy, smoking and alcoh	Preexisting Med	ical Conditions (e.	g., allergies,			
I am allergic to d	lust, but	that is t	he only		see confidentiality sec	tion on back)
allergen that I am	aware of	f. I do sm	ioke	1. Name and Address		(b) (6)
cigarettes and was	using al	bout a pac	k a			( <b>U</b> ) (U)
day. I no longer c	onsume a	ny alcohol	•			Section 1882
				Phone #	E mail	1
C. PRODUCT AVAILABILIT	v			2. Health Professional?	3 Occupation	(b) (6
roduct Available for Evaluation? (D		ct to FDA1		Yes Z No	Consumer/Other non Health prof	4. Also Reported to:
proving proving proving	ed to Manufacture			5. If you do NOT want yo	<u> </u>	Manufacturer User Facility
THE THE LET HERUM	eu io mandiacium	r on: (mm/c	dd/vyyy)		place an "X" in this box:	Distributor/Importer
ADM CO						





For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

### B5. Describe event or problem continued

ith both Propylene Glycol and Vegetable Glycerin. I tried to use their most popular flavor, which was Atomic Cinnacide and it caused my throat to get very sore and raw. I stopped using that flavor and continued to use the smoke juice in their vanilla flavor and a blend called Geoff's Blend, which tasted like Juicy Fruit gum. A short time after I discontinued using the Atomic Cinnacide flavor, I began having flu like symptoms. After these symptoms manifested themselves, I began having sinusitis and sinus infection symptoms. It has been three weeks today, since I became ill and I am still not completely well.

U.S. Department of Health and Human Services

The FDA Safety Information and

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

Internet Submission - Page 1

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FDA USE ONLY		
US-PDA-200018		
	The Section of the Control of the Co	*****************

Triage unit sequence #

Adverse Event Reporting Program Internet Submission - P	age 1		
A. PATIENT INFORMATION	D. SUSPECT PROD	OUCT(S)	
(b) (6) 2. Age at Time of Event, or 3. Sex 4. Weight		facturer (from product label)	
r Female	# E-liquid	32mg	KOV
in confidence 40 Yea Male or kg	#2		
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply.	2. Dose or Amount	Frequency	Route
1. Adverse Event Product Problem (e.g., detects/mail/unctions)	81		
Product Use Error Problem with Different Manufacturer of Same Medicine			
2. Outcomes Attributed to Adverse Event	42		The state of the s
(Check all that apply)	Dates of Use(II unknown     best estimate)	n, give duration) from/to (or	5. Event Abated After Use
Death: Disability or Permanent Damage			Stopped or Dose Reduced?
Life-threatening Congenital Anomaly/Birth Defect	#1 01/09/2012	- 01/19/2012	#1 Ves No Doesn's
Hospitalization - initial or prolonged Other Serious (Important Medical Events)	12		#2 Yes No Doesn't
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	4. Diagnosis or Reason to smoking cessa		8 Event Reappeared After
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)	#1		Reintroduction?
01/19/2012 01/22/2012	#2		#1 Yes No Doesn't
5. Describe Event, Problem or Product Use Error	6. Lot#	7. Expiration Date	#2 Yes No Doesn't
E-Cigarettes. Shortness of breath and extreme bloating.	*, NA	#1	9. NDC # or Unique ID
extreme broating.	#2	#2	NA NA
	E. SUSPECT MEDIC	CAL DEVICE	
	1. Brand Name Knockout Vapor		······································
	***************************************		1994 di min muntus angga projekti agun sadakan kan kan kan kan munas kaji san dalari (ja Susus) aga kan ka
	2. Common Device Name E-Cigarettes	MANAGEM (See State Management and Association (See Section 1988)	namen ann an agus 1 a she taghta a san a' taghta a she a' aghair a aghair a aghair a aghainn ag a bhainn a dear an ann an an an aghair a aghair a aghair a aghair a aghair a aghair a aghair a aghair a aghair a aghair a aghair a aghair
	3. Manufacturer Name, Ch Rio Rancho	y and State , New Mexico	٥
A Secretary of the Association o	4. Model #	Lot #	5. Operator of Device
RECEIVED		NA	Health Professional
ULOLIVED	Catalog #	Expiration Date (m)	m/dd/yyyy) Lay User/Patient
JAN 23 2012	Serial #	Other#	[] Other:
	6. If Implanted, Give Date (		de accessorante la congessa de popular e popular e Manager (construir de la construir de Accessorante de la construir de la co
MEDWATCH CTU	o. II implanted, Give Date (	minvod/yyyy) 7. If Exp	lanted, Give Date (mm/dd/yyyy)
WEDWAICHOLD	B. is this a Single-use Devi	ce that was Reprocessed a	and Reused on a Patient?
	Yes No	and the second s	Piliforedrotes representative and the relativistic tendos a manifestative symmetry and security relativistic tendos and the security of the se
	9. If Yes to item No. 8, Ente	er Name and Address of Re	processor
6. Relevant Tests/Laboratory Data, including Dates			
AN	*		
	F. OTHER (CONCO		
	Product names and therap	y dates (exclude treatment o	ol event)
			and the second s
Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies,			
race, pregnancy, smcking and alcohol use, liver/kidney problems, etc.)	G. REPORTER (See	confidentiality secti	on on back)
obviously a smoker, but I do not have this reaction to regular cigarettes.	1 Name and Address		5. 9179 C. 25 4.1 pt. al. 4.1
January Lagrange Court			(b) (6)
	Phone #	E-mail	
	the construction of the contract of the contra	(b) i	(6)
C. PRODUCT AVAILABILITY	2. Health Professional? 3.	<u>-</u>	4 Also Reported to:
roduct Available for Evaluation? (Do not send product to FDA)	Yes No Ot	her Health Profess	(E) Westerbest
✓ Yos No Returned to Manufacturer on:	5. If you do NOT want your		User Facility
(mm/dd/yyyy)	to the manufacturer, plac	e ari "A" in mis box;	Distributor/Importer

# FDA USE ONLY

# MEDWATCH

The FDA Safety Information and

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

Point Approved, Ond No. 09:0-0291, Expires. 10:31:06
See OMB statement on reverse.

Triage unit US-FDA-201229 sequence #

verse Event R	eporting Program	Internet Submission -	rage I			
. PATIENT INF			D. SUSPECT PR	ODUCT(S)		
Patient identifier	Age at Time of Event, or Date of Birth:	3. Sex 4. Weight 135 b	1. Name, Strongth, Ma	unulecturer (from prod	luci label)	San ("Sandana Ala
In confidence	35 Yea	Male Orkg	02	24(8)(45)(3)		
ADVERSE E	VENT, PRODUCT PRO	BLEM OR ERROR	2. Dose or Amount	Fri	squency	Route
ck all that apply:			TO Mg to		Daily	Oral
Adverse Event			"			
Product Use E	rror Problem with Differe	nt Manufacturer of Same Medicine	12			
utcomes Attribut	ed to Adverse Event		3. Dates of Use (If unk	nowa sive duration) for	amilia (or 5 Event	Abated After Use
	ne lana a man	isability or Permanent Damage	best estimate)	nown, give oblacion, ne		ed or Dose Reduced?
	(mm/dd/yyyy)	•	#1		#1 🗆 Y	es No Doesn't
Life-threatening	,	ongenital Anomaly/Birth Delect	•2			es No Doesn't
u-		ther Serious (Important Medical Events)	4. Diagnosis or Reason	on for Use (Indication)		Apply
Required Interv	rention to Prevent Permanent Im		Smoking Ce	ssation		Reappeared After oduction?
ate of Event (mm.	/dd/yyyy) 4. Dal	e of this Report (mm/dd/yyyy)			#1 🕢 v	es No Deesn't
		02/11/2012	0.1-0.0	7 Eurisetten D		C Doctor's
•	roblem or Product Use Error	h- ano h	6. Lot# ALL	7. Expiration Da	#2 U Y	es No Apply
	h (b) (6) and that the nicoti	he CEO has ne cartridges the	#1		9. NDC #	or Unique ID
	nufactures and		#2	#2	N/A	
	tes contain (b)		E. SUSPECT ME	EDICAL DEVICE		
n ingredi	ent aside form	the liquid	<sup>1. B</sup> (b) (6)			
	nd propylene gl		2. Common Device N	arne	V ( 1 )	
	t disclose the f the cartridge		<del> </del>			
		many trips to the	<sup>3</sup> (b) (6)	- Cityd Ei-th		
		n (b) (4) China,			- N. C. B. 1. N. 200 - 1. N. 2	
e knows t	hat the process	involving which	4. Model #	Lot#		5. Operator of Device
nvolves t	he building and	filling of				Health Professional
	is likely tain		Catalog #	Expiration	on Date (mm/dd/yyyy)	Lay User/Patient
1 (E. C. 1714) SERVER TO SEE PASSING A 18 P.	. My unde e contained in	rstanding) is that	Serial #	Other #		Other
		in the US contains	Series ?	Outer 9		
· · · · · · ·	<b>√</b>		6. If Implented, Give	Date (mm/dd/yyyy)	7. If Explanted, Gi	ve Date (mm/dd/yyyy)
			8. is this a Single-use		processed and Reuse	d on a Pallent?
			Yes Y No			
			9. If Yes to Item No. 8	, Enter Name and Ad	dress of Reprocesso	'
Relevant Teste/l m	boratory Data, including Date		1 1			
		porting a series of	1 1			
ide effec	ts derived from	the use of (b)	1 1			
lectronic	cigarettes. Wh	ile company				
		instructed (b)(6)	F. OTHER (CO	(COMITANT) ME	DICAL PRODUC	CTS
	ervice to tell a	all customers at those are the		therapy dates (eyclid	e treatment of event)	
eporting	stopping to smol	ke traditional	G	Smakina C	Electr	
	.(Cont)	ac croarcionar	claim(Cont	, Smoking C	essation Ar	u -AS
J				,		
Maria Data a 4 M	atana bahadhar Barralay	Indian Candidan / a citatos	4			
race, pregnancy, si	moking and alcohol use. liver/kit	ledical Conditions (e.g., allergies, tney problems, etc.)	G. REPORTER	(See confidentia	ality section on	back)
lost users	of the (b prod	luct often report	1. Name and Address	**************************************		
severe eff	ects alter use,	whether regular des, headaches	(b) (6)			
		-manifesting by				
		, asthma-, heavy	788875		1 =n	<del></del> , <del></del>
otion sid	· · · · · · · · · · · · · · · · · · ·	• •	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	889688 3704 Jan 19	E-mall	(b)
PRODUCT	AVAILABILITY		2. Health Profession	ei? 3 Occupation	1	4. Also Reported to:
	r Evaluation? (Do not send pro	oduct to FDA)	Yes 🗸 No	Consumer/Other nor	Health professional	Manufacturer
			5. If you do NOT was	t your identity disclo	sed	User Facility
🗸 Yes 🗌 N	o Asturned to Manufac	turer on:		er, place an "X" in thi		Distributor/Importer

# MED**VV**ATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

### B5. Describe event or problem continued

mixtur of propylene glycol, liquid nicotine and other flavorings. However (b)(6) assists and follows the manufacturing process which both the e-cig batteries and accessories and flavor cartridges go through, has reported himself that he would never use the product because he is aware of the contents which include (b)(4)

. He has explained that it is also present because (b) (4) My concerns are not unfounded. Most users of the 🌘 product often report severe effects after use, whether regular or irregular. which includes, headaches and migraines, allergies -manifesting by means of hives, itchiness, asthma-, heavy motion sickness, vomiting, stomach unrest, diarrhea, shortness of breath and palpitations . I have become increasingly concerned that the product our company sells is, in its current state, not suitable for human use or consumption. Especially after hearing the comments and explanations from (b)(6) regarding the product He clearly explained that because the FDA has no jurisdiction over the and its contents. products, that at the current stage, the manufacturing standards from China are so unregulated that the contents of the products will go undetected for the moment. The main argument behind this rationale is that his profits will continue to soar tremendously with such low manufacturing costs but huge profits. The company is currently importing the products through highly illegal means in the US, from (b) (4) Many of the products do not have the correct specifications or labels and many shipments have been detained and confiscated because of non-compliance. Furthermore, without knowledge of its employes, the company has been using the names and social security number of many employees to import shipments of tons of products in order to avoid customs screening. This recently resulted in US customs detaining and questioning one of said employe during her holiday travels and she had her passport confiscated upon return to the US -despite being a US citizen- as has been issued several notices by US customs. (b) (6) is willfully putting consumers at great danger and violating not only custom and import laws, but is also KNOWINGLY selling a potentially poisonous product in great quantities. The company currently makes about \$(b)(4) sales per day through its website and it distributing (b) (4) to masses without their knowledge. The long term damage is at this point unknown but will have grave consequences for consumers, according to (b) (6) oversees the manufacturing process of (b) products from our various factories in (b)(4). He oversees the conceptualization of all our products / batteries as well as the making of flavor cartridges and their contents. He has clearly stated that he has no 100% knowledge of what actually goes into the manufacturing of the flavor cartridges and that their contents have not passed minimal safety tests assessed in China, by China standards and much less by US, FDA and US Customs Standards. In addition, the majority of products imported by the company do not meet the standards required for imports in terms of labeling and safety. While the company DOES have chocking hazards warnings on its instruction manuals, the company was contacted less than 2 weeks ago regarding the death of a baby under lyr old, whom choked on a (b) flavor cartridge. (b) (4)

I believe that this company is currently a massive threat to the public because of its practices, faulty products and toxic ingredients. And that it does so knowingly at this point for the sole reason that the monetary benefits are huge while blatantly saying that it can do so without any impact and regulation from the FDA. My concerns are founded, especially since seeing a huge rise in people's complains regarding our products and the side effects they are experiencing. While it may not be clear at this point what the long terms effect of (b) (4) will be on consumers, it most certainly will become evident within a few years. And thekidney and liver damages resulting from the use of (b) (6) electronic cigarettes will be far greater than that of other toxins used and allowed by the FDA on concumer products. Again, this was stateded by whom oversees the design, manufacturing and production of (b) products.

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

or FAX to: 1-800-FDA-0178





For VOLUNTARY reporting by health professionals of adverse events and product problems Internet Submission - Page 3

### B6. Relevant tests/laboratory data, including dates continued

has epressed that he knows it is most likely due to the chemicals and toxins in the cartridges of the (b) (6) product contents, not disclosed to consumers. Yet he instructs his staff to be convincing regarding the fact that any symptoms expreiences should be associated with stopping smoking traditional cigarettes. He himself, as a heavy smoker, stated -which is on tape- that he would never use his own (b products because he knows the true and other highly toxic chemicals contents of the products which includes (b) (4) which he will not disclose on the product content but have been clea

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For VOLUNTARY reporting by health professionals of adverse events and product problems Internet Submission - Page 4

## B7. Other relevant history, including preexisting medical conditions continued

vomiting, stomch unrest, diarrhea, shortness of breath and palpitations . have been reporting a series of side effects derived fro

b customers

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



For VOLUNTARY reporting by health professionals of adverse events and product problems Internet Submission - Page 5

_	O41	Concomitant	احجناسحسا	
_		deralateralasibe labi		ATA ATA UST MILE
	<b>UNIT</b>	Conconnicant	, illiculcul	products

d in the (b) (6) website. Clearand obvius non-compliance not to advertise as a smoking cessation product-

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

Internet Submission - Page 6

no. FUA COMMENTS				7		r			<del></del>
Drug	Manufacturer	Dose	Unit	Route	•	Dosage	Frequenc interval	y Unit	ls Con- comitant
		<del>                                     </del>		<del> </del>					
	<u></u>		-	+					
		_	-	<del> </del>					
				<u> </u>					
Diagnosis fo	or Use	Start	End	Duration	Τ,	Jnit			
		Date	Date		<u> </u>				
		<del></del>		ļ					
		···.							
				<u> </u>	<u> </u>				
FDA Comments:									
WALKERC   ******* 2	012-02-13-11.01.54	1******	***					<del></del>	
USFDAMWVOLUNTARY_201229 Route To: CDRH :	: Paper	-							

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

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or FAX to:

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

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	See OMB statemer	it on reverse
7	DA LICE CALLY	

Triage unit US-FDA-202088 sequence #

The FDA Safety Inform		Internet S	ubmission - P	age 1							
Adverse Event Repor				5 011055	of prop	HOT(C)					
A. PATIENT INFORM				D. SUSPE			1.11.1.11				4
	e at Time of Event, or ie of Birth:	3. Sex	4. Weight 145 %	1. Name, Stree #1 E-Ci		e Straw		gh Gree	n Smar	t Livin	9
in confidence	35 Yea	☐ Male	Ofkg	<b>0</b> 2							
B. ADVERSE EVEN	T. PRODUCT PRO	BLEM OR ERF	ROR	L	Amount		Frequency		Route		$\dashv$
Check all that apply:			HIGH Daily Rest					<del>dicatory</del>			
1. Adverse Event	Product Problem (e.g	., defects/maifuncti	ons)	*1 113	<u> </u>				] [in]	nalation	
Product Use Error	Problem with Differen	nt Manufacturer of	Same Medicine	#2							
2. Outcomes Attributed to A	Adverse Event						<u> </u>			y of the law of the la	4
(Check all that apply)			İ	3. Dates of Un best estima		n, give duration	) from/to (or	5. Event At		r Use Reduced?	
Death: Disability or Permanent Damage		#1 01/19		- 02/2	5/2012	#1 Yes	COSC 79	<b></b> ✓ Does			
(mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect									Appl		
Hospitalization - initial	or prolonged 🗸 O	ther Serious (Import	ant Medical Events)	#2				#2 Yes	s 🔲 No	Does Apph	
Required Intervention to Prevent Permanent Impairment/Damage (Devices)			4. Diagnosis or Reason for Use (Indication) Personal use B. Event Reappeared Aft						ᅱ		
		e of this Report (m		#1 Perso	nai use				luction?		l
<ol> <li>Date of Event (mm/dd/yy)</li> <li>02/25/2012</li> </ol>	yy)	02/25/2012	inowyyyy)					#1 Yes	s 🔲 No	Does	nï
		02/23/2012		#2		J. Cu-1	. Data			Does	-1
5. Describe Event, Problem			, , ,	6. Lot #	2280	7. Expiration		#2 Yes	i L No	Appi	
I've been smo	king the E-c	igarette f	or about	9201112280 #1 1		#1 12/28/	12/28/2012		9. NDC # or Unique ID		
a month now,				#2	#2	8808			8		
these e-cigar				E. SUSPECT MEDICAL DEVIC			E				
sound every t lasted for ab				1. Brand Nam Green							-
hear the whee				Green	Smart L	iving					
lately I have				2. Common C	evice Name	arette					
with nausea a											
I didn't pay	much attention	on to it,	but	324 S	400 W	<b>ty and State</b> Suite 1!	50 Salt	t Lake	City,	UT	
today after i	nhaling the	e-cigarett	e I felt	84101							
extreme nause				4. Model #		Lot #			. Operato	r of Device	
throughout my body accompanied with			S801 & S808		9201	9201112280 for refi		Healt	h Profession	al	
weakness, dis				Catalog #		1 '	ation Date (m		[] Lavi	lser/Patient	
breathing. I told my husband that I didn't feel good. I woke to find myself on the bathroom floor and my husband calling			S801 & S808 12/28/201			Other:					
			Serial # Other # Not sure \$801 & \$808				Personal Use				
pathroom 1100	r and my nus	band call	ing	Not sure				planted, Give	Date (ma	· (cleta na )	
				O. II HTSPANIAL	D, GIVE DEIS	(mm/dd/yyyy)	/. # EA	pianieu, Grec	Dete (ros)	//ouryyyy/	
				8 is this a Si	ngie use Des	vice that was i	Reprocessed	and Reused	on a Patie	ent?	-
				Yes	☑ No						
				9. If Yes to It		ter Name and	Address of R	leprocessor			
											-
6. Relevant Tests/Laborate	ory Date, Including Date:	1									
None											
				1							
				F. OTHE	R (CONCC	MITANT)	MEDICAL	PRODUCT	'S		
				Product nan	nes and ther	py dates (exc	dude treatmen	it of event)			
				Green	Smart I	Living I	Recharg	eable S	_	. <b></b>	
						igarette			& Re	eruei	
				Now re	ILLIS S	5 pack 1	#19DOP	>808			
l				1 1							
7. Other Relevant History,	Including Preexisting M	edical Conditions	(e.g., aliorgies,	0.000	DTER (A		- 1: - 1:1				
race, pregnancy, smoking Allergic to K	and alcohol use, liver/kid leflex Medica		casional			ee confider	mainty sec	tion on ba	ICK)		
smoker and dr				1. Name and (b) (		No.					
issues that I						AAC					
				1 1							
					(- <del></del>		1,200 (2,300) 1,200 = 1			**	
1				Phone #			ilem 3				(b)
S 22001-07 1-1-1	LABULITY.			2. Health Pro	fessional?	3. Occupation	n	4.	Also Rep		
C. PRODUCT AVAIL		4 -4 - 50 -		Yes	'	Consumer/Other		1	Manul		
Product Available for Eval	wetten? (Do not send pro	quel (o FUA)			<b>₩</b>					Facility	
☑ Yes ☐ No	Returned to Manufac	turer on:				ur identity dis		Z	=	outor/Import	o,
			nm/dd/yyyy)	to the max	RESCUENT, P	lace an "X" in	INIS DOX:	T.	L. DISTRE	лиотипроп	e٢





For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

### B5. Describe event or problem continued

m name, continued to feel disoriented, but this time having difficulty speaking. I was slurring...I had passed out. I was having difficulty moving my body as it felt extremely heavy, my hands and feet felt as if I were having a tremendous body spam causing my hands to curl in, as seen on patients with Cerebral Palsy. It was EXTREMELY scary specially since I do not really have health issues. I am not sure if this was caused by the e-cigarette, but I do not have any other explanation to this mornings incident.



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

Internet Submission - Page 6

Drug	Manufacturer	Dose	Unit	Route	Frequency Dosage Interval Unit		is Con- comitant	
<del></del>								
			1	· · · · · · · · · · · · · · · · · · ·				

Diagnosis for Use	Start Date	End Date	Duration	Unit

## **FDA Comments:**

WILSONJ:  ******* 2012-02-27-10.00.31	******
USFDAMWVOLUNTARY_202088_14727_20120226.xml	
Route To: AERS : Electronic	
Route To: DQRS : Paper	
Route To: CDRH : : Paper	
Need Copy for CTP	
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