The FDA Safety Information and

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

Internet Submission

Form Approved: OMB No. 0910 See Off	0-0291, Expires: 10/31/04 MB statement on reverse
FDA USE ONL	_Y
Triage unit sequence #	
CT(S)	
ner (from product label) 3 0 mg	
Frequency	Route
All day .	

Adverse Event Reporting Program		
A. PATIENT INFORMATION		
1. Patient Identifier 2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) (b) (6)	Female	or "
in confidence 27 Years	Male	kg
B. ADVERSE EVENT, PRODUCT PRO Check all that apply:	BLEM OR ERRO	JK
		. 1
Adverse Event Product Problem (e.g. Product Use Error Problem with Difference Problem with Diffe		
2. Outcomes Attributed to Adverse Event	nt manufacturer or 5	ame Medicine
(Check all that apply)		
Death: Death:	sability or Permanent	Damage
(mm/dd/yyyy) Life-threatening	ongenital Anomaly/Bir	th Defect
	her Serious (Importar	nt Medical Events)
Required Intervention to Prevent Permanent Im	pairment/Damage (De	evices)
3. Date of Event (mm/dd/yyyy) 4. Dat	e of this Report (mm	/dd/vvvv)
(b) (6)	06/26/2013	
5. Describe Event, Problem or Product Use Error		
On March 15, 2013 I starte	d using th	e vapor
E cigarette. After a few v		
E cigarette I ended up in	the hospit	al ER on
(b)(6) and another time		
ear congestion and hearing		
time I started using the I now I lost my hearing in m		
high pitch noise that neve		
Before I started using the		
never had any problems wit		
doctor believes I will nev	ver have my	hearing
back in my left ear.		I
1		
	CTI:	
	CTU	
		2040
	CTU JUN 27	2013
		2013
		2013 Mora
6. Relevant Tests/Laboratory Data, Including Dates	JUN 27	
	JUN 27	Mors
I have had two hearing tea	JUN 27	Mors
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further	JUN 27	Mors on also
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the	JUN 27	Mors on also ith a
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several med	JUN 27	Mors on also ith a
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the	JUN 27	Mors on also ith a
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several med	JUN 27	Mors on also ith a
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several med	JUN 27	Mors on also ith a
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several means teroids which have not hear 1. Other Relevant History, including Preexisting Means (b) (6) in the I have been on several means (c) (c) (d) (d) (d) (d) (d) (d) (d) (e) (e) (e) (e) (e) (e) (e) (e) (e) (e	st done one (b) (6) testing we next week dications a	Mora on also ith a or so. nd
I have had two hearing term (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several means teroids which have not he	st done one (b) (6) testing we next week dications a	Mora on also ith a or so. nd
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several means teroids which have not hear 1. Other Relevant History, including Preexisting Means (b) (6) in the I have been on several means (c) (c) (d) (d) (d) (d) (d) (d) (d) (e) (e) (e) (e) (e) (e) (e) (e) (e) (e	st done one (b) (6) testing we next week dications a	Mora on also ith a or so. nd
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several means teroids which have not hear 1. Other Relevant History, including Preexisting Means (b) (6) in the I have been on several means (c) (c) (d) (d) (d) (d) (d) (d) (d) (e) (e) (e) (e) (e) (e) (e) (e) (e) (e	st done one (b) (6) testing we next week dications a	more on also ith a or so. nd
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several means teroids which have not hear 1. Other Relevant History, including Preexisting Means (b) (6) in the I have been on several means (c) (c) (d) (d) (d) (d) (d) (d) (d) (e) (e) (e) (e) (e) (e) (e) (e) (e) (e	st done one (b) (6) testing we next week dications a	more on also ith a or so. nd
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several measurements which have not hear 1. Other Relevant History, including Preexisting Measurements.	st done one (b) (6) testing we next week dications a	Mora on also ith a or so. nd More
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several means teroids which have not hear t	st done one (b) (6) testing we next week dications a	more on also ith a or so. nd
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several means teroids which have not hear ace, pregnancy, smoking and alcohol use, liver/kide. 7. Other Relevant History, including Preexisting Marace, pregnancy, smoking and alcohol use, liver/kide.	st done one (b) (6) testing we next week dications as elped.	Mora on also ith a or so. nd More
I have had two hearing team (b) (6) & (b) (6) and a MRI blood work. I have further specialist in (b) (6) in the I have been on several means teroids which have not hear t	st done one (b) (6) testing we next week dications as elped.	Mora on also ith a or so. nd More

- Page 1						
D. SUSPECT PROD	LICT(S)					
1. Name, Strength, Manufa		roduct label)				
Vapor e cigaret	te 30mg					
#2						
2. Dose or Amount		Frequency		Route		
#1 26 mg] [All day	•			
#2						
3. Dates of Use (If unknown	, give duration)	from/to (or		Abated After Use		
best estimate) #1 03/15/2013	05/1	3/2013	,	ed or Dose Reduced?		
				Apply		
#2 03/15/2013		3/2013	#2 🗌 Y	es No Doesn't		
4. Diagnosis or Reason for To stop smokin				Reappeared After oduction?		
#1				es No Doesn't		
#2	I			Apply		
6. Lot#	7. Expiration	Date	#2 🗌 Y	es No Doesn't		
#1	#1		9. NDC #	or Unique ID		
#2	#2	<u> </u>				
E. SUSPECT MEDIC	CAL DEVIC	E				
1. Brand Name E cig		·				
2. Common Device Name						
3. Manufacturer Name, Cit	y and State					
Naples vapor, Cap	-	Florida				
4. Model #	Lot #			5. Operator of Device		
4. MOUGH #	201#					
Catalog #	Expira	tion Date (mn	n/dd/yyyy)	Lay User/Patient		
. 0 - 1 - 1 -				Other:		
Serial #	Other					
6. If Implanted, Give Date	mm/dd/yyyy)	7. If Expl	anted, Giv	e Date (mm/dd/yyyy)		
8. Is this a Single-use Devi	ice that was R	eprocessed a	nd Reused	d on a Patient?		
9. If Yes to Item No. 8, Ente	er Name and A	ddress of Re	processor			
F. OTHER (CONCO	MITANT) M	EDICAL P	RODUC	TS		
Product names and therap						
				88220893Dasa		
C DEDORTED (C		to lite		More		
G. REPORTER (See	confident	iality secti	on on b	ack)		
(b) (6)						
Phone # (b) (6)		E-mail (b) (6))			
\-\\\-\\\\-\\\\\\\\\\\\\\\\\\\\\\\\\\\	Occupation	(3) (0)	<u>/</u>	Also Reported to:		
Yes 🔽 No				Manufacturer		
5. If you do NOT want your	Identity disci	osed		User Facility		
to the manufacturer, pla				Distributor/Importer		

(mm/dd/yyyy)

The FDA Safety Information and

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

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See OMB	statement on	
EDA LICE ONLY		

Triage unit sequence #

dverse Event Reporting Program			
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	ufacturer (from product label)	
b) Date of Birth: Female 185 lb (b) (6)	#1		
In confidence V Male Kg	#2		
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	2. Dose or Amount	Frequency	Route
Check all that apply:	#1		•
Adverse Event Product Problem (e.g., defects/malfunctions)	"		
Product Use Error Problem with Different Manufacturer of Same Medicine	#2		
Outcomes Attributed to Adverse Event (Check all that apply)	3. Dates of Use/if unknow	wn, give duration) from/to (or	5. Event Abated After Use
Death: Disability or Permanent Damage	best estimate)	, , , , , , , , , , , , , , , , , , ,	Stopped or Dose Reduced?
(mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect	#1		#1 Yes No Doesn't
Hospitalization - initial or prolonged Other Serious (Important Medical Events)	#2		#2 Yes No Doesn't
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	4. Diagnosis or Reason f	for Use (Indication)	Apply
	#1		8. Event Reappeared After Reintroduction?
Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 07/10/2013	#0		#1 Yes No Doesn't
Describe Event, Problem or Product Use Error	#2 6. Lot #	7. Expiration Date	- Doesn't
	6. Lot #	7. Expiration Date	#2 Yes No Apply
When coworker uses electronic cigarrette, I	#1	#1	9. NDC # or Unique ID
get a burning sensation in my lungs and irritation in my eyes.	#2 .	#2	
in any of op.	E. SUSPECT MED	ICAL DEVICE	
	1. Brand Name UNKNOWN		
	2. Common Device Name	e	
	Electronic Ciga		
	3. Manufacturer Name, C UNKNOWN	Jity and State	
	ONKNOWN		
	4. Model #	Lot #	5. Operator of Device
			Health Professional
	Catalog #	Expiration Date (m	nm/dd/yyyy) Lay User/Patient
	Serial #	Other#	Other:
	001131.11		
	6. If Implanted, Give Date	e (mm/dd/yyyy) 7. If Ex	planted, Give Date (mm/dd/yyyy)
	8. Is this a Single-use De	evice that was Reprocessed	and Reused on a Patient?
	tund tund	nter Name and Address of R	enrocessor
More	0. 11 100 10 1011 110. 0, 21	nor mario and Addition of the	0003401
. Relevant Tests/Laboratory Data, Including Dates			
	F. OTHER (CONC	OMITANT) MEDICAL	PRODUCTS
	Product names and then	rapy dates (exclude treatment	t of event)
More			200 00000000000000000000000000000000000
Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies.			More
race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)		ee confidentiality sec	tion on back)
I am a non-smoker and no one in my household	1. Name and Address (b) (6)		
smokes. My employeer bars the use of cigarettes in the facility, but does not bar	(-)(-)		
the use of electronic	(b) (6)	(b)	(b) (6)
printed	Phone #	E-mail	
More		(b) (b)	·
C. PRODUCT AVAILABILITY		3. Occupation	4. Also Reported to:
roduct Available for Evaluation? (Do not send product to FDA)	Yes V No		Manufacturer
Yes No Returned to Manufacturer on:	5. If you do NOT want yo	our identity disclosed	User Facility Distributor/Importer
(mm/ddhunu)	i was manulaciorer. D	JOSEPH A IN UNIS DOX:	DISTIDUTORII



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

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B7. Other relevant history, including preexisting medical conditions continued

cigarettes.

Mail to: MEDWATCH

5600 Fishers Lane Rockville, MD 20852-9787

or FAX to:

1-800-FDA-0178





DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Form Approved: OMB No. 0910-0291 Expiration Date: 6/30/2015 (See PRA Statement on preceding general information page)

MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

Section A -	About the Problem
What kind of problem was it? (Check all that apply)	Did any of the following happen? (Check all that apply)
 ✓ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker 	Hospitalization – admitted or stayed longer Required help to prevent permanent harm (for medical devices only) Disability or health problem Birth defect Life-threatening Death (Include date):
Date the problem occurred (mp)(dd)(and) 4/11/3 FIND	Other serious/important medical incident (Please describe below)
Tell us what happened and how it happened. (Include as many IN HPRILI HAD BEEN USING CIE MY GRANDDAUGHTER. GOT UF THING HND HAD BLURED VIS	details as possible) On HAD ECIG. WHEN I WAS AROUND OF FORILIST AND KEPT DROPPING TON. THOUGHT IT HIGHT BEOMETICAN Page
List any relevant tests or laboratory data if you know them. (Incl	
For a problem with a product, including prescription or over-the-counter medicine biologics, such as human cells and tissues used for trans (for example, tendons, ligaments, and bone) and gene the nutrition products, such as vitamins and minerals, herbal formulas, and medical foods cosmetics or make-up products foods (including beverages and ingredients added to foods)	splantation herapies Go to Section B I remedies, infant
For a problem with a medical device, including any health-related test, tool, or piece of equipment health-related kits, such as glucose monitoring kits or blue implants, such as breast implants, pacemakers, or cathe other consumer health products, such as contact lenses breast pumps	eters (Skip Section B)

For more information, visit http://www.fda.gov/MedWatch

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

	Continued Entries	
CONTINUED ENTRY FOR: Tell us y	What happened and how it happened. (Included DATTELL PHYOME, ON IN STARTING TO GET ON MENT TO THE SOIL WAS DINGNED TO THE SOIL WAS DINGNED.	de as many details as possible)
A MINI STROKE, P	TA GOODS AS TO ST	HAD DEAN
PEACIG + ECIG	LA STATISTING B GET	VERY AND THE PAY INDE
WAS GOING ALL	DOD PIFH HAD I COU	THE ED ACTER
SIGN MY NAM	E SO I WENT 101	AL EN, APIESS
BNP MANYTE	EST I WAS DINGNE	SED HE NICOTINE
LOAD, SO THEY	Cost ME# 2,000. To	FIND OUT.
) (302, 111 1, 27000	
		ž.
CONTINUED ENTRY FOR: List any	relevant tests or laboratory data if you know	v them. (Include dates)
CONTINUED ENTRY FOR: List all a	urrent prescription medications and medical	I davisas haira was
CONTINOLD ENTRY FOR. LIST OF	unent prescription medications and medical	devices being used.
CONTINUED ENTRY FOR: List all or	ver-the-counter medications and any vitamir	ns, minerals, and herbal remedies being

		Section B	- About the Products	
Name of the product as it app SAVEASMOKE		the box, bottle, or packa	age (Include as many nam	es as you see)
Name of the company that ma	kes the	product		
Expiration date (mm/dd/yyyy)		Lot number		NDC number
Strength (for example, 250 mg per 500 mL or 1 g) 18 HG, E Liquid	2 puffs,	y (for example, 2 pills, or 1 teaspoon, etc.)	Frequency (for example twice daily or at bedtime ALL DAY	by mouth, by injection, or on the skin)? INHILED
Date the person first started to or using the product (mm/dd/) Date the person stopped takin using the product (mm/dd/yyy	yyy): 💆]/27/13/03/31) (6)	supposed to treat?)	Ing the product (such as, what condition was it If To GET HWAY FROM
Did the problem stop after the person reduced the dose or s taking or using the product?		Yes □ No	BUT STILL	GET NICOTINE
Did the problem return if the pthe product again?	erson st	arted taking or using		duct in case we need to evaluate it? (Do not . We will contact you directly if we need it.)
∑⊠ Yes 🗌 N	10 <u></u>	Didn't restart	⊠ Yes	s 🗌 No
☐ Go to Section D	(Skip Se	ection C)		
Name of medical device Name of the company that ma		medical device	About the Medical Devi	piration date, if you can locate them)
			· · · · · · · · · · · · · · · · · · ·	
Was someone operating the	If yes	who was using it?		
medical device when the problem occurred?	1 _	The person who had the	problem	
Yes		A health professional (se Someone else (<i>Please</i> e	uch as a doctor, nurse, or explain who)	aide)
∐ No	_	, , , , , ,		
For implanted medical device	s ONLY	(such as pacemakers,	breast implants, etc.)	
Date the implant was put in (nm/dd/y	yyy)	Date the implant w	vas taken out (If relevant) (mm/dd/yyyy)
☐ Go to Section D				

For more information, visit http://www.fda.gov/MedWatch

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

		Sectio	CONTRACTOR CONTRACTOR CONTRACTOR	SCALL STATE OF THE SECOND STATE	ho Had the Pro	5.00 to 10.00 to 10.00 to 10.00 to 10.00 to	
Person's Initials (b) (6)	Sex	Female	Age (at time occurred) or		Weight (Specify lbs or kg)	Race	
		Male Male	66		175	W	
ist known medica					er, heart disease	, or others)	
Please list all allerg	NE				agnancy alcohol	use etc)	
SMOKE	R				synancy, alconor		
List all current pres アドソムの	<u> </u>		medical devices	being used.			
			NA RECORD				Continuation Page
List all over-the-co		-		'		medies being	used. Continuation
☐ Go to		Tax and tax an					
	Su a Airean	ilo. Swarpesta ero Efrica av 200				and the sections	WAS DOWN IN A CONTROL OF THE STATE OF
We will contact you	u only if w		and the second of the second	Asset of the artists of the Santan and	illing Out This ot be given out to		
ast name(b) (6)				Fi	rst name		***************************************
		·			b) (6)		
Number/Street (b) (6)		- 1	•	City a (b)	nd State/Province (6)		
Country (b) (6)				1	Postal code (6)		
(b) (6)	-		Email address (b) (6)	S			Today's date (mm/dd/yyy)
Did you report this (the manufacturer)	?		that makes the p		akes the product		nformation to the company r) to help them evaluate the
				Report by i			
eep the product i lail or fax the forr		he FDA wants to	o contact you fo	or more inforn	nation. Please de	o not send pr	oducts to the FDA.
5600 F			Fax: 1-800-332	2-0178 (toll-free	>)		
		Than	k you for help	ing us protec	ct the public he	alth.	
For more informa	ntion, visi	t http://www.fda.g	gov/MedWatch	I	•		e an admission that medical ontributed to the event.

Triage unit sequence #

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY recording (P) adverse events, product problems and product use errors

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т гррготоч.	VIII D			statement	
	FDA	USE	ONLY		

A. PATIENT IN					Dose or Amount		Frequen		Route	
	2. Age at Time of Event or Date of Birth:	3. Se x	4. Weight	#1			Once d	aily	Inhalat.	ion
(b) (6)	30 Years	✓ Female	100 lb				<u> </u>			
In confidence	(b) (6)	Male	orkg	#2						
	EVENT, PRODUCT PRO	BLEM OR ER	ROR		ites of Use (if unknown best estimate)	wn, give	duration)	from/to		Abated After Use or Dose Reduced?
Check all that apply: 1. Adverse Even	t Product Problem (e.g	a defects/malfunct	tions)		week					es No Doesn
Product Use E			*	#2					#2 Y	es No Doesn
2. Outcomes Attrib (Check all that ap	uted to Adverse Event				agnosis or Reason for recreational	for Use	(Indication	n)		Apply Reappeared After
Death:	✓ Disat	ility or Permanent	Damage	_					Reint	roduction? 'es No Doesn
Life-threatening	<i>(mm/dd/yyyy)</i> g ☐ Cong	enital Anomaly/Birt	h Defect	#2						Apply
	- initial or prolonged Other			6. Lo	t #	7. E	xpiration	Date		es No Doesn
	vention to Prevent Permanent I		` '	#2		-1			9. NDC 1	# or Unique ID
3. Date of Event (m.		of this Report (m	nm/dd/yyyy)		CUCRECT	#2	DEV.			· · · · · · · · · · · · · · · · · · ·
		07/2013			SUSPECT MEDI	ICAL	DEVICE			
	Problem or Product Use Errong a disposable EonSr		nic	1. Br	and Name					
cigarette re	egularly for about a	week, I deve	eloped a							
middle of th	ubercular-sounding cone night with coughin	ng fits multi	ple times.	2. Co	mmon Device Name	e				
	ner cold symptoms wha my behavior had chanc									
	was the product.	, dill		3. Ma	nufacturer Name, C	ity and	State			
				4 M	odel#		ot#			5. Operator of Device
				7. 1	Mei #	-	OC#			Health Professiona
				-	talog #		vnjestic-	Date /m-	/dd/sees	
			•	"	talog #		.xpiration	Date (mm	raaryyyy)	Lay User/Patient
6 Relevant Tests#	aboratory Data, Including Da	toe								Other:
o. Relevant 165(5/L	aboratory bata, including ba	1 0 3		Se	rial #	٥	other#			
				6. If I	mplanted, Give Date	• (mm/a	id/yyyy)	7. If Exp	lanted, G	ive Date (mm/dd/yyyy)
					this a Single-use De	vice th	at was Re	processe	d and Re	used on a Patient?
					es to item No. 8, Ente	er Name	and Addr	ess of Rep	rocessor	
7. Other Relevant H	istory, including Preexisting	Medical Condition	ns (e.g							
allergies, race, pre	egnancy, smoking and alcohol of Medical Conditions:	ise, liver/kidney pro	oblems, etc.)							
Important In	nformation: drinks re				THER (CONCO					
OTC Meds: n	/a			Prod	uct names and thera	apy dat	es (exclud	ie treatmei	nt of even	t)
					REPORTER (See	conf	identiali	ty sectio	on on ba	ack)
C. PRODUCT A	VAILABILITY				me and Address me: (b) (6)					
	or Evaluation? (Do not send p	roduct to FDA)			me: (b) (c) dress:					
Yes Vo	Returned to Manufacture		ddanna							
D. SUSPECT P	RODUCT(S)	(mm/	dd/yyyy)	Cit	y:			State	e: Z II	P:
	Manufacturer (from product lab	pel)		Phon	e #			E-mail		
	ke Electronic Cigare							(b) (6)		
Strength:	-			0 ::	-M- B(-)	0.0:				
Manufacturer: Ec	onsmoke LLC			1 _	alth Professional?	J. UCCI	upation		4.	Also Reported to:
#2 Name: Strength:					Yes No	- lad ***				Manufacturer User Facility
Manufacturer:					ou do NOT want your the manufacturer, plac					Distributor/Importer
									ı	,

PLEASE TYPE OR USE BLACK INK

Form Approved: OMB N **FDA USE ONLY**

Triage unit sequence #

MEDWATCH

The FDA Safety Information and

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

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Ю,	091	0-029	1, Exp	oires:	12/	31/201
	See	OMB	state	ment	on	reverse

Adverse Event Reporting Program	age 1 01 4		L					
A. PATIENT INFORMATION	2.	Dose or Amount	Frequen	cy Route				
1. Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight Date of Birth:								
(b) (6) Date of Birth: 44 Years 7 Female 25	0 lb 40			_				
(b) (6)	#2 kg #2	•						
In confidence		ates of Use (If unknown	give duration)	from/to 5 Ever	nt Abated After Use			
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply:	(0	or best estimate)		Stoppe	d or Dose Reduced?			
1. ✓ Adverse Event Product Problem (e.g., defects/malfunctions)	11	03/01/2012 - 08/2	22/2012	#1 🗸	Yes No Doesn't			
Product Use Error Problem with Different Manufacturer of Same Med				#2 □	Yes No Doesn't			
2. Outcomes Attributed to Adverse Event	11	iagnosis or Reason for)	Apply It Reappeared After			
(Check all that apply) Death: Disability or Permanent Damage	"'	Thought they wo than smoking.	ura ne sai	Rein	troduction?			
(mm/dd/yyyy)	#2	2		#1 []	Yes No Doesn't			
 ✓ Life-threatening ✓ Congenital Anomaly/Birth Defect ✓ Hospitalization - initial or prolonged ✓ Other Serious (Important Medical Ev 	(ants) 6. L	ot#	7. Expiration I	Date #2	Yes No Doesn't			
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	/ents) #1		#1		# or Unique ID			
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)	#2		#2		-			
(b) (6) 08/09/2013		SUSPECT MEDIC	AL DEVICE					
5. Describe Event, Problem or Product Use Error	11	rand Name						
I am not sure but after smoking e-cigs for about 6 months I ended up with blood clots in my lungs. The								
could not find a reason for then still calling them	2. C	ommon Device Name						
unprovoked. I just wanted it to be out there in case others share the same fate. Maybe there is a	se							
correlation between e-cigs and blood clots????	3. N	lanufacturer Name, City	and State					
		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,					
	4. N	lodel#	Lot#		5. Operator of Device			
					Health Professional			
	-	atalog #	Expiration	Date (mm/dd/yyyy	Lay User/Patient			
	"	aurog #	LAPITACION	-acc (mindaryyyy				
6. Relevant Tests/Laboratory Data, Including Dates					Other:			
Unprovoked blood clots. EKG's, echo-cardiograms,	[]	erial #	Other#					
numerous blood tests, artery scans, lung scans, now am on blood thinners for an undetermined amount of				r				
time because they were unprovoked. They said I could	d 6. If	6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy)						
have died.	8. Is	this a Single-use Devi	ce that was Re	processed and R	eused on a Patient?			
		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 Addr	ess of Reprocesso	r			
 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc., 								
allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc., Race:White Medical Conditions: Just some depression	l	OTHER (CONOC)	ALT A NATURAL	DICAL BROS	HCTC			
until this happened. Allergies: Sulfa products		OTHER (CONCON duct names and therap						
Important Information: Used to smoke RX Meds: Proza Seroquel, now on coumadin OTC Meds:	c, Pro	auct names and therap	y dates (excido	e treatment of eve	nuj			
•								
		REPORTER (See o	onfidentiali	ty section on l	oack)			
C. PRODUCT AVAILABILITY		lame and Address	_					
Product Available for Evaluation? (Do not send product to FDA)		address: (b) (6)						
Yes No Returned to Manufacturer on:	^	() ()						
(mm/dd/yyyy)	c	city: (b) (6)		State:(b) z	_{IP:} (b) (6)			
D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product label)	Pho	one#		E-mail				
#1 Name: E-cigs	(b)	(6)		(b) (6)				
Strength:	2 1	lealth Professional? 3.	Occupation	<u> </u>	4. Also Reported to:			
Manufacturer:	11	Yes No	Occupation	ľ	Manufacturer			
#2 Name: Strength:		you do NOT want your is	dentity disclose	d	User Facility			
Manufacturer:		o the manufacturer, place			Distributor/Importer			

PLEASE TYPE OR USE BLACK INK

The FDA Safety Information and

Consumer Report

Triage unit sequence #

For VOLUNTARY report adverse events, product'problems and

product use errors

rom Approved:	OMB NO.	0910-029	i, Expires.	12/31/201
		See OMB	statement	on reverse

Adverse Event I	Reporting Program		Page-	1-01-2	' '/)			
A. PATIENT IN				I - ·	Dose or Amount	Freque	ncy Rout	e
	Age at Time of Event or Date of Birth:	3. Sex	4. Weight	#1				
o)	24 Years	Female	139 _{lb}	"_				
		✓ Male	or kg	#2	15ml			
In confidence	CVENT PROPUSE P			1	too of the officers		- E E	vent Abated After Use
neck all that apply:	EVENT, PRODUCT PF	KOBLEW OR E	RRUR		ates of Use (If unknown, r best estimate)	give duration)		pped or Dose Reduced?
Adverse Even	t Product Problem (e.g., defects/malfund	ctions)	#1 0	8/17/2013 - 08/1	9/2013	#1	Yes No Does
	rror Problem with Diffe	•		#2 0	8/16/2013 - 08/1	9/2013	#2	✓ Yes No Does
	uted to Adverse Event			1	agnosis or Reason for	•	n)	Appl
(Check all that app		-1 'P1 D	B	#1	smoking alterna	tive		Event Reappeared After Reintroduction?
Death:	mm/dd/yyyy)	ability or Permanent	Damage	#2	smoking alterna	tive	#1	✓ Yes No Does
Life-threatenin		ngenital Anomaly/Bir		<u> </u>			#2	✓ Yes No Does
	- initial or prolonged Oth			6. Lo		7. Expiration #1		Apply
	vention to Prevent Permanen				ku: LMT13	#2	^{9.} N	NDC # or Unique ID
Date of Event (m		ate of this Report (mm/dd/yyyy)	l				
08/19/2013		/19/2013			SUSPECT MEDIC rand Name	AL DEVIC	=	
,	Problem or Product Use En ng an e-cigarette,		quickly		-cigarette			
that it did	have an adverse ef	fect on my lu	ng		wasakan e			
	he device itself (m leaked the fluid ve			11'	ommon Device Name -cigarette			
exposure to	my lips and tounge	. The fluid t	hat was	•	-cigarette			
	oduced by MAYA Elec				anufacturer Name, City	and State		
container.	ne menthol flavored	e-iidnia in	a IOMI	G	l			
					odel#	Lot#		5. Operator of Devi
				H H	oney eGo-CE5			Health Profession
				C	atalog #	Expiration	Date (mm/dd/	(yyyy) Lay User/Patient
					aosimai			
Relevant Tests/I	aboratory Data, Including [Dates		ا ا	vial#	Other #		Other:
NA				8	erial#	Other #		
								W-1124
				6. If	Implanted, Give Date (r	mm/dd/yyyy)	7. If Explant	ed, Give Date (mm/dd/yyy)
				8 le	this a Single-use Devie	ce that was R	eprocessed an	d Reused on a Patient?
					Yes No	- January Week	.p. 2300000 an	
				9. If	Yes to Item No. 8, Enter I	Name and Add	ress of Reproce	essor
Other Relevant H	listory, Including Preexistin	ng Medical Condition	ons (e.a.	1				
allergies, race, pre	egnancy, smoking and alcoho	oł use, liver/kidney p	roblems, etc.)	IL	·			
	Medical Conditions: : RX Meds: OTC Me		important		OTHER (CONCOM			
				Proc	luct names and therap	y dates (exclu	de treatment of	event)
				G	REPORTER (See o	onfidential	ity section	on hack)
					ame and Address	omicomia.	ney Section C	on buony
	AVAILABILITY				ame: Fake Name			
roduct Available f	for Evaluation? (Do not send	d product to FDA)		A	ddress:			
Yes ✓ No	Returned to Manufactu	rer on:	n/dd/yyyy)	Ш				
. SUSPECT P	RODUCT(S)	(11111	1111/	C	ty:		State:	- ZIP:
	Manufacturer (from product	label)		Pho	ne#		E-mail	
Name: Honey	eGo-CE5							
Strength: NA Manufacturer: G	aceimai			2. H	ealth Professional? 3.	Occupation		4. Also Reported to:
				11 _	Yes No			Manufacturer
Strength: 24mg	d Refill Menthol F	Lavor			you do NOT want your id	lentity disclos	ed	User Facility
	AYA Electric Smoke				the manufacturer, place			Distributor/Import

Consumer Report

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

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

The FDA Safety Information and

FDA USE ONLY

Triage unit sequence #

Ad	verse Event l	Reporting Program	///	Pag e 1	of 2						
Α.	. PATIENT IN	IFORMATION				Dose or Amount	Frequen	cy Route			
1. P	atient Identifier	Age at Time of Event or Date of Birth:	3. Sex	4. Weight	#1						
(b)		25 Years	✓ Female	115 _{lb}	#2		٦				
	la sant i	(b) (6)	Male	or kg	""						
	In confidence	EVENT, PRODUCT PR	I OBLEM OR ER		3. Da	tes of Use (if unknown,	give duration)		nt Abated After Use		
	eck all that apply:	, , , , , , , , , , , , , , , , , , ,			(01	best estimate)		Stopp	ed or Dose Reduced?		
1. [✓ Adverse Even	_	-	- 1	#1			#1 [Yes No Doesn't		
	Product Use E	rror Problem with Differe	nt Manufacturer o	f Same Medicine	#2		Mar Wartarda	#2	Yes No Doesn't Apply		
	Outcomes Attrib (Check all that ap	uted to Adverse Event		İ	4. Dia	agnosis or Reason for	use (Indication	8. Eve	nt Reappeared After		
- 1	Death:	_	bility or Permanent	Damage	l _				ntroduction? Yes No Doesn't		
1	Life-threatenin	mm/dd/yyyy)	enital Anomaly/Birt	h Defect	#2			#1 L	Apply		
- 1		- initial or prolonged 🔲 Othe			6. Lo		7. Expiration	Date #2	Yes No Doesn't		
		vention to Prevent Permanent			#1		#1 	9. ND	C # or Unique ID		
3.	Date of Event (m	m/dd/yyyy) 4. Dat	e of this Report (n	nm/dd/yyyy)	#2		#2				
(b) (6)		23/2013			SUSPECT MEDIC	AL DEVICE				
		Problem or Product Use Erro		on obost		and Name erando eGo-C Sli	n				
	heavyness ar	ter using Torando eG nd pain occurred. 3-	days after th	nis started							
	an emergency	y room visit was mad I was released in th	e where I was	s kept		ommon Device Name	m				
Ž	diagnosis of	f pneumonia. I was s	ent home for	rest and	10	Tando ego-c SIII	M.				
X	given anti-	piotics				nufacturer Name, City	and State				
Ą					JE	ACVAPOUR					
E E											
SE					4. Mo	odel#	Lot#		5. Operator of Device		
N N									Health Professional		
					Ca	talog#	Expiration	Date (mm/dd/yyy	y) Lay User/Patient		
TYPE									Other:		
日 日 6.		aboratory Data, Including Da , blood tests.	ites		Se	rial#	Other#				
PLEASE	onest n-ray	, 21000 00000.									
FC					6. If I	mplanted, Give Date (r	nm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yyyy)		
					8 le	this a Single-use Devic	e that was Re	processed and I	Reused on a Patient?		
					Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No No						
					9. If Yes to Item No. 8, Enter Name and Address of Reprocessor						
7.	Other Relevant H	listory, Including Preexisting	Medical Condition	ns (e.g.,							
	allergies, race, pr	egnancy, smoking and alcohol Medical Conditions:	use, liver/kidney pr	oblems, etc.)		THE CONCOL	ITANIT ME	DICAL BROOK	NICTO		
	Important I	nformation: None RX				OTHER (CONCOM					
	Daily Vitam	ın			'''	ac, names and therap	, autos (excitit	o treatment of ev	o.ny		
						REPORTER (See came and Address	onfidentiali	ty section on	back)		
C.	PRODUCT	AVAILABILITY				ame: (b) (6)					
Pr	oduct Available	for Evaluation? (Do not send	product to FDA)			dress: (b) (6)					
	Yes No	Returned to Manufacture		/dd/yyyy)							
D.	SUSPECT P	PRODUCT(S)	tum.	1111/	l	ty: (b) (6)		State: (b	zip: (b)		
1.	Name, Strength,	Manufacturer (from product la	ibel)		Phor	ne #		E-mail (b) (6)			
#1	Name: Strength:							(0) (0)			
	Manufacturer:				2. He	ealth Professional? 3.	Occupation		4. Also Reported to:		
#2	Name:					Yes No			Manufacturer		
	Strength:					you do NOT want your id the manufacturer, place			User Facility Distributor/Importer		
1	Manufacturer:				II ¹⁰	and manageruses, place	un A 111 U118		- Programatory uniborter		

The FDA Safety Information and

Consumer Report

For VOLUNTARY reporting CTP adverse events, product use arrest product use errors

Page 1 of 2

rem Approves. OND	statement	

Triage unit sequence #

Adverse E	Event Re	porting Progr	ram		rage	1 01 2							
A. PATI	ENT INF	ORMATION				2.	Dose or Amount		Frequency	Route			
1. Patient Ide		Age at Time of E	vent or	3. Sex	4. Weight	#1]				
(b)		Date of Birth:		Female	235 _{lb}		L]				
		b) (6)		✓ Male	or ka	#2		,					
In confide					kg				<u> ال</u>				
	designation between the	ENT, PRODU	CT PRO	OBLEM OR ER	ROR		ates of Use (If unknown best estimate)	wn, give	e duration) fro		ent Abated A ped or Dose F		
Check all that		Product Dec	hlem /e /	g., defects/malfunct	tions)	#1 0	1/05/2013 - 08	/12/2	2013	1	Yes No	Doesn't	
1		_		ן., טפופכנציוומוזמוזכנ nt Manufacturer o		#2					٠	Apply	
la contraction of the contractio		d to Adverse Eve				4. D	agnosis or Reason I	for Use	(Indication)	,	Yes No	Apply	
	ii that apply					#1	used it to we	een o	ff of		ent Reappear		
Death:		n/dd/yyyy)	Disak	pility or Permanent	Damage	#2	cigarettes			1	Yes No	Doesn't	
✓ Life-th		waaryyyy)	Cong	enital Anomaly/Birt	th Defect	"*						Apply	
				Serious (Importan		6. Lo	ot#		xpiration De	ite #2	Yes No	Doesn't Apply	
Requir	red interver	ntion to Prevent Pe	rmanent i	mpairment/Damage	e (Devices)	#1		#1		9. NC	C # or Uniqu	e ID	
3. Date of E	vent (mm/	dd/yyyy)	4. Date	e of this Report (n	nm/dd/yyyy)	#2		#2					
(b) (6)			08/	26/2013			SUSPECT MED	ICAL	DEVICE				
		blem or Product				1. B	rand Name						
				ral months wh e feeling of									
out. h	eart ra	te was slow	to the	point of bla	acking out.	2. C	ommon Device Name	е					
went to	o er wa r. they	s released as caught seve	nd had ral ev	to wear a ho ents from fas	olter st erratic								
beats	sometim	es my heart	was add	ding beats th	nat were	3. M	anufacturer Name, C	ity and	State				
out of	rhythm	and others	were si	low were i sl product and i	kipped a its been ?								
weeks.	no mor	e issues. i	am wear	ring an event	t monitor								
				not noticed a ing using pro		4. M	odel#	1	_ot#		5. Operat	or of Device	
not on		i have the .		rud mariid bic	/ducc. 50						Health	n Professional	
R	-					<u> </u>	stalog #		Evniration D	ate (mm/dd/yy	W	ser/Patient	
8						"	atalog #	'	Expiration D	ace (minicolyy)			
2				A							Other:	;	
6. Relevant		oratory Data, inci or showed e	_	tes beats(48 hi	r worn)	S	erial#	1	Other#				
Y someti	mes add	ing or missi	ng bear	ts blood pre	essure is								
good.		good, chole	sterol	good. psa go	ood. non	6. If	Implanted, Give Dat	e (mm/	dd/yyyy) 7	7. If Explanted	Explanted, Give Date (mm/dd/yyyy)		
ataber.							this a Single-use De	le= 21	ant was Bre		Dayman on -	Dation42	
							this a Single-use De	avice ti	iat was Kepi	ocessed and	Reused On a	racientí	
						<u> </u>	Yes to Item No. 8, Ent	er Nam	e and Addres	s of Reproces	sor		
	1	han bak was		Madinal Ossadin	/								
allergies,	race, pregi	nancy, smoking and	d alcohol	Medical Condition use, liver/kidney pr	oblems, etc.)								
Race:W	Vhite Me	dical Condit	ions:	NONE Allergie Information	es:	F.	OTHER (CONC	MITA	NT) MED	ICAL PRO	DUCTS		
quitti	ing smok	ing. rare a	lcohol	use RX Meds	: NONE OTC	Proc	duct names and ther	apy da	tes (exclude	treatment of e	vent)		
Meds:	multi	vitamin											
						G	REPORTER (See	0.000	fidoptiolit	soction or	hack)		
				-			ame and Address	e com	nuemianity	360(1011 01	Dack)		
		AILABILITY				N	ame:(b) (6)						
Product Av	ailable for	Evaluation? (Do I	not send p	product to FDA)		A	ddress: (b) (6)						
✓ Yes	☐ No	Returned to Ma	anufacture	er on:	/dd/yyyy)								
D. SUSP	ECT PR	ODUCT(S)		(iiiii		C	_{ity:} (b) (6)			State (b)	ZIP: (b)		
		nufacturer (from)	product la	bel)			ne #		- 1	E-mail			
#1 Name: I						(b)	(6)			(b) (6)			
Strength	n: high cturer: BLU	,				2. H	ealth Professional?	3. Occ	upation		4. Also Rep	orted to:	
#2 Name:	Marer. BLU			····		П	Yes No				I — '	facturer	
#2 Name: Strength	1 :					ــــا ا	you do NOT want you	ır ident	ity disclosed			Facility	
Manufac							the manufacturer, pl				Distrit	outor/Importer	

U.S. Repertment of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

(SONTINUATION BAGE) For VOLUNTARY reporting of adverse events and product problems

Page 2 of 2

B.5. Describe Event or Problem (continued) feeling of passing out and feeling as if I was dying (seriously) i am now out \$1700 and counting for my er and doctor visits I still have the product in my possession i would love for someone to
analyze what is in this product. I was going to the gym walking 3 miles on treadmill. lifting etc that all stopped once the event occurred. been worried of having a heart attack. I was having heart
palpitations every day until roughly 10 hrs after stopping use of product. the I felt like a rush of energy hit me and started to feel better
+
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of Padverse events, product problems and Paroduct use errors

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	See OMB statement on reverse
	FDA USE ONLY
Triage unit sequence #	

Adverse Event I	Reporting Progr	ram		Page	' ⁽⁾ {						
A. PATIENT IN	FORMATION					Dose or Amount		Frequency	Route		
1. Patient Identifier	2. Age at Time of E Date of Birth:	vent or	3. Sex	4. Weight	#1]		
o) (6)	64 Years		√ Female	190 _{lb}	,,,,			<u> </u>			
	(b) (6)		Male	or kg	#2						
In confidence	EVENT, PRODU	CT DD			3. Da	ites of Use (If unkno	wn, aive	duration) fro	m/to 5. Ever	nt Abated After	
neck all that apply:	-VENT, PRODU	O I PKI	SECIM ON EN	.KOK	(0	r best estimate)	, 3111		Stoppe	ed or Dose Rec	luced?
Adverse Even		, ,	g., defects/malfunct		#1				#1 🔲	Yes No	☐ Does Apply
	rror Problem wi	th Differe	nt Manufacturer o	f Same Medicine	#2			4 1 0	#2 🔲	Yes No	Does
Outcomes Attrib	uted to Adverse Eve	ent			4. Di	agnosis or Reason	tor Use	(Indication)	8. Ever	nt Reappeared	After
Death:	~-3/	Disal	bility or Permanent	Damage					Rein	troduction?	☐ Does
	mm/dd/yyyy)	_	enital Anomaly/Birt	-	#2				#1 <u> </u>	Yes No	Apply
Life-threatening	g - initial or prolonged				6. Lc	ot #	7. E	xpiration Da	#2	Yes No	Does
_	- Initial or prolonged vention to Prevent Pe		, ,		#1		#1	,		# or Unique II	
Date of Event (m.			e of this Report (m		#2		#2			•	
08/31/2013	*****		03/2013		E.	SUSPECT MED	ICAL	DEVICE			
Describe Event.	Problem or Product	Use Erro	or		1. Br	rand Name					
Kissing my	partner who wa	s usin	g an e-cigare	ette caused							
me to get "painful.	orgmented cont	act ch	erticis. Mulc	Tu is very	2. C c	ommon Device Nam	10				
•											
					3 M	anufacturer Name,	City and	State			
					J. W.	aaiaetaiei ivailie, i	ony and				
					4. M	odel#		Lot#		5. Operator	of Devi
										Health P	
					_	atalog #	- ,	Expiration D	ate (mm/dd/yyy)	y) Lay Use	r/Patient
					"	atalog #	'	-xpiration Di	ute (mmuunyyy)		,, auciil
Dalaussa Tosas "	aborate Data III-	luding D	stoc							Other:	
. neievant Tests/L	aboratory Data, Inc	raung Da	1149		S	erial #		Other#			
					6. If	Implanted, Give Da	te (mm/	(dd/yyyy) 7	. If Explanted,	Give Date (mn	n/dd/yyyy
					8. Is	this a Single-use D	evice tl	hat was Repr	rocessed and F	Reused on a Pa	atient?
						Yes No					
					9. If	Yes to Item No. 8, En	ter Nam	e and Addres	s of Reprocess	or	
Other Relevant H	listory, Including Pr	reexisting	Medical Condition	ns (e.g.,							
allergies, race, pr	egnancy, smoking an Medical Condit	nd alcohol	use, liver/kidney pr	oblems, etc.)						11030	
sensitivite	sformaldehy	de	-			OTHER (CONC					
	smoke causes graines. Impo				Proc	duct names and the	rapy da	nes (exclude	ueaunent of eve	entj	
OTC Meds:	grained, impor			.3							
						REPORTER (Se	e con	fidentiality	section on	back)	
PRODUCT	AVAILABILITY					ame and Address					
	for Evaluation? (Do	not send	product to FDA)			ame:(b) (6) ddress:(b) (6)					
TYes □ No	Returned to M		er on:		^'	QQ1000. (-) (0)					
			(mm	/dd/yyyy)	,	_{ity:} (b) (6)			State:(b)	ZIP:	
). SUSPECT F		product !	ahel)		l ——	ne #		7	E-mail		
. Name, Strength, 1 Name: E-Ciga	Manufacturer (from arette	product la	inel)						(b) (6)		
Strength:						- Nh Darf 1 12	اء م	aumatic :		4 Alex Person	tod to:
Manufacturer:						ealth Professional?	3. Oc	cupation		4. Also Repor	
Name:					ļ	Yes No	ur idas	ity disclosed		User Fa	
Strength: Manufacturer:						you do NOT want yo the manufacturer, p				Distribut	•
. Horizandoror											

The FDA Safety Information and Adverse Event Reporting Program

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

Page 1 of

FDA USE ONLY
Triage unit sequence #

Adverse Event Reporting Program			
A. PATIENT INFORMATION	2. Dose or Amount		Route
1. Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight	#1 unkown	Four times daily	
(b) Date of Birth: 45 Years Female	#2		
(b) (6)	#2		
In confidence	3. Dates of Use (if unknown,	give duration) from/to	5. Event Abated After Use
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	(or best estimate)		Stopped or Dose Reduced?
Check all that apply: 1. Adverse Event Product Problem (e.g., defects/malfunctions)	#1 04/04/2011 - 09/0	5/2013	#1 Yes No Doesn't
Product Use Error Problem with Different Manufacturer of Same Medicine	#2		#2 Yes No Doesn't
2. Outcomes Attributed to Adverse Event	4. Diagnosis or Reason for		8. Event Reappeared After
(Check all that apply)	#1 not a user; i go smoke from e-ci		Reintroduction?
Death: Disability or Permanent Damage	#2		#1 Yes No Doesn'
Life-threatening Congenital Anomaly/Birth Defect		7 Evaluation Pate	#2 Tyes No Doesn't
Hospitalization - initial or prolonged Other Serious (Important Medical Events)	1	7. Expiration Date #1 09/04/2013	Apply
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	#1 uknown #2	#2	9. NDC # or Unique ID
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)	E. SUSPECT MEDIC		
09/04/2013 09/05/2013	1. Brand Name	DEVICE	
5. Describe Event, Problem or Product Use Error I get constant headaches at work from various e-cigs			
smokes indoors. I have to move frequently 2-3 times a	2 Common Barris		
day to get away from various e-cig smokers. I have repeatedly asked Human Resources to help over a year	2. Common Device Name		
and a half, but have not received any assistance or			
policy change.	3. Manufacturer Name, City	and State	
¥			
<u>B</u>	1	-	E Orașeta (5)
ISE CONTRACTOR OF THE CONTRACT	4. Model #	Lot #	5. Operator of Device Health Professional
and a half, but have not received any assistance or policy change.			Health Professional
0	Catalog #	Expiration Date (m.	m/dd/yyyy) Lay User/Patient
			Other:
	Serial #	Other#	
several doctor visits related to nausea			
<u>PE</u>	6. If Implanted, Give Date (mm/dd/vvvv) 7 if Ev	xplanted, Give Date (mm/dd/yyyy)
<u>a.</u>			
		ice that was Reprocess	sed and Reused on a Patient?
	Yes No	Name and Address of D	eprocessor
	J . II 165 to Item No. 6, Enter	WILL WALLES OF K	
 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) 			
Race: White Medical Conditions: none Allergies:	F. OTHER (CONCON	MITANT) MEDICAL	PRODUCTS
mountain cedar Important Information: none RX Meds: none OTC Meds:	Product names and therap		
none Olo Meds.			
			tion on book
	G. REPORTER (See	confidentiality sec	uon on back)
C. PRODUCT AVAILABILITY	1. Name and Address Name:(b) (6)		
Product Available for Evaluation? (Do not send product to FDA)	Address: (b) (6)		
Yes No Returned to Manufacturer on:			
(mm/dd/yyyy)	City: (b) (6)	St	tate:(b) ZIP: (b)
D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product label)	Phone #	E-mail	
#1 Name: e-cig	(b) (6)	(b) (6	0)
Strength: unknow	2. Health Professional? 3	Occupation	4. Also Reported to:
Manufacturer: unkown	Yes No		Manufacturer
#2 Name: Strength:	5. If you do NOT want your	identity disclosed	User Facility
Strength: Manufacturer:	to the manufacturer, place	e an "X" in this box:	Distributor/Importer

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Triage unit sequence #

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		SAA OMR	etatement	on reverse

	Adverse Event F	Reporting Prog	jram		rage	012							
	A. PATIENT IN	FORMATION				2.	Dose or Amount	-	Frequenc	у	Route		
	1. Patient Identifier	2. Age at Time of I	Event or	3. Sex	4. Weight	#1			7				
	(b)	Date of Birth:		✓ Female	190 _{lb}								
		67 Years (b) (6)		T T Ciliale		#2			<u> </u>				
	In confidence	(b) (d)		Male	orkg	ll	1						
	B. ADVERSE E	VENT PRODI	JCT PRO	OBLEM OR ER	ROR	3. Da	ites of Use (If unk	nown, giv	re duration)	from/to	5. Even	t Abated Aft	er Use
i	Check all that apply:	VENT, I ROBE		JULIAN ON LI	N.O.		r best estimate)		, , , , , ,		Stopper	d or Dose R	
	1. Adverse Event	t Product Pr	roblem (e.	g., defects/malfunct	ions)	#1					#1 🔲 Y	res No	Doesn't Apply
		rror Problem w		•	-	#2					1		Doesn't
	2. Outcomes Attribu	stad to Adverse Ev	ont			4. Di	agnosis or Reaso	n for Us	e (Indication)	#2 L	res ∐ No	Apply
	(Check all that app					#1						t Reappeare	d After
	Death:		✓ Disal	oility or Permanent	Damage	II _					_	roduction?	☐ Doesn't
		mm/dd/yyyy)	Cons	enital Anomaly/Birt	h Defect	#2					#' 🗀 '	res 🗀 No	Apply
	Life-threatening	•		•		6. L o		17	Expiration (Date	#2 [7]	res No	☐ Doesn't
		- initial or prolonged				#1		#1	-xpii auoii i	Juito	0.1100		Apply
	Required Interv	vention to Prevent P	ermanent i	mpairment/Damage	e (Devices)	#2	YARIN				9. NDC	# or Unique	IU
	3. Date of Event (mr	m/dd/yyyy)	4. Dat	e of this Report (n	nm/dd/yyyy)	1 L		#2					
	07/15/2013		09/	12/2013		E.	SUSPECT ME	DICAL	DEVICE				
	5. Describe Event, F	Problem or Produc	t Use Erro	r		11	rand Name						
	In an attemp	t to quit sme	oking I	got the e-ci	gs. After	e	-cig						
		se, I noticed I a very sick				1	ommon Device Na	·me					
\checkmark		have congest					-ciq						
TYPE OR USE BLACK INK	e-cigs were	the only this											
¥	line. I foun	nd on their or betes, heart p				3. M	anufacturer Name	, City an	d State				
AC	you had diab	use. What abo				e e	-cig						
퓠	are attempti	ng to quit s											
E	pregnant? Wh	at problems				4 M	odel#		Lot#			5. Operato	r of Device
S	a few years?	If I had not use the	t known	my body so w	iell,	'' '''							Professional
2	Continued to	ase the											riologgional
0						C	atalog #		Expiration	Date (mn	n/dd/yyyy)	Lay Us	er/Patient
PE												Other:	
	6. Relevant Tests/La	aboratory Data Inc	cluding Da	ites		-	-1-14		Other #			Other.	
띬	o. Neievant 165ts/L	abolatory Data, Int	cidding Da	103		5	erial #		Other #				
Ą						Ш							
PLEASE						6. If	Implanted, Give D	ate (mm	/dd/yyyy)	7. If Exp	olanted, C	Sive Date (m	m/dd/yyyy)
-						Ш	•						
							this a Single-use	Device t	hat was Re	processe	d and Re	eused on a F	atient?
i						Yes No							
						9. If	Yes to Item No. 8, I	Enter Nan	ne and Addr	ess of Re	processo	r	
	7. Other Relevant Hi	istory. Including P	reexisting	Medical Condition	ns (e.a	11							
	allergies, race, pre	egnancy, smoking a	nd alcohol	use, liver/kidney pro	oblems, etc.)	П							
		Medical Condi				F.	OTHER (CON	COMIT	ANT) ME	DICAL	PRODU	JCTS	
		ergies: milk avix, Furosem					luct names and ti						
		etformin OTC			,	Ш							
						Ш							
						G.	REPORTER (S	See con	fidentiali	tv secti	on on b	ack)	
							ame and Address						
	C. PRODUCT A					l N	ame: (b) (6)						
	Product Available for	or Evaluation? (Do	not send p	product to FDA)		A	ddress: (b) (6)						
	Yes No	Returned to M	lanufacture	er on:		П							
				(mm	/dd/yyyy)	_	ty: (b) (6)			Stat	te:(b z	_{IP:} (b)	
	D. SUSPECT P					Pho				E-mail	2		
	1. Name, Strength, I	Manufacturer (from	product la	bel)		(b)				(b) (6)		
	#1 Name:					(~)	(-)			(~) (0	,		İ
	Strength: Manufacturer:					2. H	ealth Professiona	1? 3. Oc	cupation		4	. Also Repo	rted to:
				··		JI _	Yes No					✓ Manufa	
	#2 Name: Strength:							rous id-	tibu dinata-	d		User Fa	
	Manufacturer:						you do NOT want y the manufacturer,				1 1	=	tor/Importer
						ш ~		-		_	, 1		

(CONTINUATION PAGE)

For VOLUNTARY reporting of adverse events and product problems

The FDA Safety Information and Adverse Event Reporting Program

MEDWATCH

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B.5. Describe Event or Problem (continued) e-cig and had a heart attack, would they have paid my bill? They should be required to post the same information in the store that is on-line. I shudder to think of the problems down the roadl
same information in the store that is on-line. I shudder to think of the problems down the road!
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
÷
F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)
i des Wi

Consumer Report

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

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The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting adverse events, product problems and
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11.

FDA USE ONLY
Triage unit sequence #

Adverse Event I	Reporting Program		<i>[</i>	1012						
A. PATIENT IN	IFORMATION				Dose or Amount	Frequen	cy Route			
	Age at Time of Event or Date of Birth:	3. Sex	4. Weight	#1						
(b)	42 Years	√ Female	150 _{lb}							
	(b) (6)	Male	or kg	#2						
In confidence	THE PROPERT OF			0.0	A Elle - //E		francia de Eve	nt Abated After Use		
Check all that apply:	EVENT, PRODUCT PR	OBLEW OR E	RKOK	3. Da	tes of Use (If unknown, r best estimate)	give duradon)	Stopp	ed or Dose Reduced?		
1. Adverse Even	t Product Problem (e	.g., defects/malfund	tions)	#1 13	1/01/2012 - 09/2	0/2013	#1 🗸	Yes No Doesr		
. –	rror 🔲 Problem with Differ	ent Manufacturer	of Same Medicine	#2			#2	Yes No Doesr		
	uted to Adverse Event			1	agnosis or Reason for another attempt	•	1)	Apply ent Reappeared After		
(Check all that ap)		bility or Permanent	Damage	"'	smoking	co quit	Rei	ntroduction?		
	mm/dd/yyyy)	genital Anomaly/Bi	-	#2			#1 🛂	Yes No Doesr Apply		
Life-threatening	o - initial or prolonged ✓ Othe	•		6. Lo	t#	7. Expiration	Date #2	Yes No Doesn		
	vention to Prevent Permanent			#1		#1	9. ND	C#or Unique ID		
		te of this Report (#2		#2				
(b) (6) Event /m	09.	/21/2013		E.	SUSPECT MEDIC	AL DEVICE				
	Problem or Product Use Err	or		1. Br	and Name					
	seness, raspy voice. hleghm. Headaches.	Increased a	mount of							
mucus and pr	nrogim. neadaones.			2. Cc	ommon Device Name					
				3. Ma	anufacturer Name, City	and State				
3				4. Mc	odel#	Lot#		5. Operator of Device		
								Health Professions		
				Ca	italog#	Expiration	Date (mm/dd/yy)	y) Lay User/Patient		
								Other:		
	aboratory Data, Including D	ates		Se	erial #	Other#				
				6. If	Implanted, Give Date (mm/dd/yyyy)	7. If Explanted	Give Date (mm/dd/yyyy)		
1										
				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				
7 Other Palauant II	lietone Including Proceints	Madical Condition	ne /e a							
	listory, Including Preexisting egnancy, smoking and alcoho									
	Medical Conditions: nformation: smoked				OTHER (CONCOM					
OTC Meds: n		-		Prod	luct names and therap	y dates (exclud	de treatment of ev	rent)		
					REPORTER (See o	confidential	ty section on	back)		
C. PRODUCT	AVAIL ABILITY				ame and Address					
	for Evaluation? (Do not send	product to FDA)		11	ame: (b) (6) ddress:					
Yes No	Returned to Manufactur	er on:		```						
D. SUSPECT P	PRODUCT(S)	(mr	n/dd/yyyy)	Ci	ty:		State:	ZIP:		
	Manufacturer (from product)	abel)		Phor			E-mail			
#1 Name: e-ciga	* *	•								
Strength: Manufacturer:				2. He	ealth Professional? 3.	Occupation	<u> </u>	4. Also Reported to:		
#2 Name:				1	Yes No			Manufacturer		
Strength:				5. If	you do NOT want your i			User Facility		
Manufacturer:					the manufacturer, place			Distributor/Importe		

Health Care Professional

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

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sequence #	997.57p.2009.00000 1-		

Adverse Event Reporting Program	1012					
A. PATIENT INFORMATION	2. Dose or Amount	Frequency	Route			
1. Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight	#1					
(b) (6) Date of Birth: 3 Years Female Ib						
(b) (6)	#2					
In confidence Male or 20 kg						
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	3. Dates of Use (If unknown,	give duration) from/to	5. Event Abated After Use			
Check all that apply:	(or best estimate)		Stopped or Dose Reduced?			
1. Adverse Event Product Problem (e.g., defects/malfunctions)	#1		#1 Yes No Doesn't			
Product Use Error Problem with Different Manufacturer of Same Medicine	#2		#2 Yes No Doesn't			
2. Outcomes Attributed to Adverse Event	4. Diagnosis or Reason for	Use (Indication)	Apply			
(Check all that apply)	#1		8. Event Reappeared After Reintroduction?			
Death: Disability or Permanent Damage	#2		#1 Yes No Doesn't			
(mm/dd/yyyy) ☐ Life-threatening ☐ Congenital Anomaly/Birth Defect	** 2		Apply			
☐ Hospitalization - initial or prolonged Other Serious (Important Medical Events)	6. Lot#	7. Expiration Date	#2 Yes No Doesn't			
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	#1	#1	9. NDC # or Unique ID			
	#2	#2	- S. NOO W OF ORINGE ID			
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) (b) (6) 09/24/2013						
0372472013	E. SUSPECT MEDIC	AL DEVICE				
5. Describe Event, Problem or Product Use Error This 3 year old male was restrained in a car seat, in	I. DIBIIO NAINE					
the rear seat of his mothers vehicle. While she was						
driving the e-cigarette she was charging, in the	2. Common Device Name		***			
factory charge, suffered a catastrophic failure and	e-cigarette					
Z the e-cigarette expelled the copper coils out of the tube. The superheated copper coils richocheted off of						
the ceiling of the car and into the patients car seat,	3. Manufacturer Name, City	and State				
setting his trousers on fire. The fire was	Name: White Rhino City: State:	Zip:				
subsequently extinguished . The patient suffered burns to his left elbow, left flank, and left buttocks.						
S and left buccocks.	4. Model #	Lot#	5. Operator of Device			
			Health Professional			
ől l						
Tactory charge, suffered a catastrophic failure and the e-cigarette expelled the copper coils out of the tube. The superheated copper coils richocheted off of the ceiling of the car and into the patients car seat, setting his trousers on fire. The fire was subsequently extinguished. The patient suffered burns to his left elbow, left flank, and left buttocks.	Catalog #	Expiration Date (mr	n/dd/yyyy) Lay User/Patient			
<u> </u>			Other:			
6. Relevant Tests/Laboratory Data, Including Dates	Serial #	Other#				
A S						
PLEASE AND AND AND AND AND AND AND AND AND AND		1				
<u>a</u>	6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy)					
	8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?					
	Yes No					
	9. If Yes to Item No. 8, Enter Name and Address of Reprocessor					
			Ž.			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)						
	F. OTHER (CONCOMITANT) MEDICAL PRODUCTS					
	Product names and therapy dates (exclude treatment of event)					
	G. REPORTER (See co	onfidentiality cost	on on backl			
	1. Name and Address	muchilality Secti	on on back)			
C. PRODUCT AVAILABILITY	Name: (b) (6)					
Product Available for Evaluation? (Do not send product to FDA)	Address: (b) (6)					
Yes No Returned to Manufacturer on:	(3) (3)					
(mm/dd/yyyy)	City: (b) (6)	C	te:(b) ZIP: (b)			
D. SUSPECT PRODUCT(S)	Phone #		(D) ZIP: (D)			
1. Name, Strength, Manufacturer (from product label)	(b) (6)	E-mail (b) (6	1			
#1 Name: White Rhino E-Cigarette Strength:	(2) (2)	(b) (d				
Manufacturer:	2. Health Professional? 3. 0	Occupation	4. Also Reported to:			
#2 Name:	The state of the s	r Health Professional	Manufacturer			
Strength:			User Facility			
Manufacturer:	If you do NOT want your ide to the manufacturer, place a		Distributor/Importer			
2000	l line in the later in the later in					

	Section B	- About the Products	NO. Section 1			
Name of the product as it appo	ears on the box, bottle, or packa	age (include as many names a	as you see)			
CLEAN CI	a Regular	18mg	-			
Name of the company that ma	ikes the product					
Clean C	'a rm		2)			
Expiration date (mm/dd/yyyy)	Lot number	N	DC number			
NONE						
Strength (for example, 250 mg per 500 mL or 1 g)	Quantity (for example, 2 pills, 2 pulls, or 1 teaspoon, etc.)	Frequency (for example, twice daily or at bedtime)	How was it taken or used (for example, by mouth, by injection, or on the skin)?			
18 mg	600 PUFFS	No LIMIT	BY MONTH			
Date the person first started to or using the product (mm/dd/)		supposed to treat?)	the product (such as, what condition was it			
Date the person stopped takin using the product (mm/dd/yyy		TO STOP	SMOJKEIN 67			
Did the problem stop after the person reduced the dose or staking or using the product?			7			
Did the problem return if the p the product again?		Do you still have the product in case we need to evaluate it? (Do not send the product to FDA. We will contact you directly if we need it.)				
Yes N	la Didn't restert	☐ Yes ∠				
Go to Section D	(Skip Section C)					
Name of the company that ma		New Cast Market Profes				
Other identifying Information (The model, catalog, lot, serial, o	or UDI number, and the expire	ation date, if you can locate them)			
Was someone operating the medical device when the	If yes, who was using it?					
problem occurred?	The person who had the	problem				
Yes	A health professional (s	uch as a doctor, nurse, or aid	n)			
□ No	Someone else (Please o	explain who)				
For implanted medical device	s ONLY (such as pacemakers,	breast implants atc)	Paranta de la companya del companya de la companya del companya de la companya de			
Date the implant was put in (s			taken out (If relevant) (mm/dd/yyyy)			
Co to Section D						
		te lace				

For more information, visit http://www.fda.gov/MedWatch

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

Section DAbout the Person Who Had the Problem								
Person's Initials (b) (6)	Sex Fema	Age (at time occurred) or		leight (Specify s or kg) 185	Race WHIT	T .		
List known medical	List known medical conditions (such as diabetes, high blood pressure, cancer, heart disease, or others)							
COPY	>							
Please list all allerg	ies (such as to drugs	s, foods, pollen, or ot	hers).					
List any other impor	rtant information abo	ut the person (such	as smoking, pregr	ancy, alcohol use	, etc.)			
List all current pres	cription medications	and medical devices	being used.		\	M		
			-					
List all over-the-cou	inter medications an	d any vitamins, mine	rals, supplements	, and herbal reme	dies being used.			
Go to	Section E	, a litraturos tra e a	e dia mangani i	ent arginists on	and the same of the same			
	The state of the s	iction B- About		PERSONAL PROPERTY OF THE PROPE		1.3		
Last name (b) (6)	only if we need add	itional information. Y		name	e puore.	· · · · · · · · · · · · · · · · · · ·		
Number/Street (b) (6)	,		City and	State/Province				
			(b) (t	ostal code				
Country U.S.A	ar.	-	(b) (6)	ISLAN COOLE				
Telephone number (b) (6)		(b) (6)				date (mm/dd/yyyy) 3-26/3		
Did you report this problem to the company that makes the product (the manufacturer)?				that makes the product (manufacturer) to help them evaluate the				
Yes	[A])No			N A				
Send This Report by Mail or Fax Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA. Mail or fax the form to:								
5600 Fis	tch Id Drug Administration In the Standard (Inc.) In the Inc.) In the		2-0178 (toli-free)					
Thank you for helping us protect the public health.								
For more information, visit http://www.fda.gov/MedWatch Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.								