Receipt No: RCT-85212 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2017-60683 | Department: CFSAN | RCT No.: RCT-85212 | CTU Triage Date: 20-09-2017 | Total Pages:

asic Deta	ails		40.00.00.00	1000		
company l	Jnit	CDER-CTU	Originating Account	FAERS		
ource Me	dium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority		Routine				
DA Recei	ved Date	20-Sep-2017	CTU Received Date	20-Sep-2017		
TU Triage	Date					
eport Typ	е	Spontaneous	Report Classification	Drug		
ssign To		User				
ser/Group	)					
orward to	Department	CDER (CDER-	OSE-RSS-CTU@fda.hhs.gov) (E2B)			
			201 1100 010 @11011110.3017 (1115)			
ontact			25.7			
ase	First Name	Last Name	Email Address	Phone		
teporter	/b///2/	75.70	W-3-703	W. V. (0)		
<b>a</b>	(b) (6)	(b) (6)	(b) (6)	(b) (6)		
otion A	- About the Problem		- 13			
	nd of problem was it? all that apply)	Were hurt or had a ba	ad side effect (including new or worsening sympto	oms)		
(Check	all that apply)		rectly which could have or led to a problem			
		Noticed a problem wi	th the quality of the product			
		Had problems after s	witching from one product maker to another make	er		
Did any	of the following happen?					
	all that apply)	Hospitalization - admitted or stayed longer				
(Oncon	an arat apply)	Required help to prevent permanent harm (for medical devices only)				
		Disability or health problem				
		■ Birth defect				
		Life-threatening				
		Death				
		Other serious/importa	ant medical incident			
Later Brown, Lab St.	erious/important medical	Acute Myeloid Leuk	emia			
incident Data the	e problem occurred	10-Feb-2017				
1			1.1			
_	CALLED MISSELFE CO.		de as many details as possible)			
			aighteners to remove formaldehyde from			
of Kerat	in Complex by Coppola re	emoved formaldehyde	, and replaced it with other toxic ingred	ients that when heated with the		
flat iron	which is required during	this treatment, emits for	ormaldehyde. I was diagnosed with Acu	ute Myeloid Leukemia and I am		
			ct during a 6-7 time period.	The state of the s		
			The Carte of Mark Court I			
st any re	levant tests or laborate	ory data if you know	v them (Include dates)			
ection B	- About the Products			1 of 1		
	f the product as it	Keratin Complex by	Coppola			
appears	on the box, bottle,					

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 $\textbf{CTU No.: FDA-CDER-CTU-2017-60683} \ | \ \textbf{Department: CFSAN} \ | \ \textbf{RCT No.: RCT-85212} \ | \ \textbf{CTU Triage Date: 20-09-2017} \ | \ \textbf{Total Pages: 20-09-2017} \ | \ \textbf{Total Pages: 20-09-2017} \ | \ \textbf{CTU No.: RCT-85212} \ | \ \textbf{CTU Triage Date: 20-09-2017} \ | \ \textbf{Total Pages: 20-09-2017} \ | \ \textbf{CTU No.: RCT-85212} \ | \ \textbf{CTU Triage Date: 20-09-2017} \ | \ \textbf{CTU No.: RCT-85212} \ | \ \textbf{CTU Triage Date: 20-09-2017} \ | \ \textbf{CTU No.: RCT-85212} \ | \ \textbf{CTU Triage Date: 20-09-2017} \ | \ \textbf{CTU No.: RCT-85212} \ | \ \textbf{CTU Triage Date: 20-09-2017} \ | \ \textbf{CTU No.: RCT-85212} \ | \ \textbf{CTU Triage Date: 20-09-2017} \ | \ \textbf{CTU Triage D$ 

or package (Include as many names as you see) Name of the company that Coppola Beauty LLC makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Yes **Expiration date** Lot number NDC number If Other Strength If Other Quantity Frequency If Other How was it taken or used If Other Date the person first started taking or using the product Date the person stopped taking or using the product Did the problem stop after the No person reduced the dose or stopped taking or using the product? Did the problem return if the Doesn't Apply person started taking or using the product again? Do you still have the product in No case we need to evaluate it? Why was the person using the product? (such as what condition was it supposed to treat) Hair straightening Section C - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model# Catalog # Serial # Lot#

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 $CTU\ No.:\ FDA-CDER-CTU-2017-60683\ |\ Department:\ CFSAN\ |\ RCT\ No.:\ RCT-85212\ |\ CTU\ Triage\ Date:\ 20-09-2017\ |\ Total\ Pages:\ PCT\ No.:\ RCT-85212\ |\ PCT\ No.:\ RCT-85212\ |\ PCT\ No.:\ PCT-85212\ |\ PCT\ No.:\ PCT-85212\ |\ PCT\ No.:\ PCT-85212\ |\ PCT-$ 

	Unique Identifier (UDI) #						
	Expiry Date						
	Was someone operating the medical device when the problem occurred?						
Fo	or implanted medical devices C	NLY (such as pacemake	rs, breast implants, etc.)				
D	ate the implant was put in		Date the implant was taken out (If relevant)				
Se	ection D - About the Person Wh	no Had the Problem					
	Person's Initials	(b) (6					
	Sex						
	Age (specify unit of time for age)	52 Year(s)					
	Date of Birth						
	Weight	63 kg(s)					
	Ethnicity (Choose only one)	Not Hispanic/Latino					
	Race (Check all that apply)	American Indian or Alaskan Na	ative				
		Native Hawaiian or Other Paci					
		Asian					
		White					
		Black or African American					
	st known medical conditions (S	such as diabetes, high blo	od pressure, cancer, heart diseas	se or others)			
	Product caused Acute Myeloid Leukemia and needs to be taken off the market.						
	Product caused Acute Myeloid Le	ukemia and needs to be take	n off the market.				
	Product caused Acute Myeloid Le	ukemia and needs to be take	n off the market.	,			
	Product caused Acute Myeloid Le	ukemia and needs to be take	n off the market.				
	Product caused Acute Myeloid Le	ukemia and needs to be take	n off the market.				
PI							
PI	ease list all allergies (such as t						
PI							
PI	ease list all allergies (such as t						
Pl	ease list all allergies (such as t						
	ease list all allergies (such as t N/A	o drugs, foods, pollen or	others)				
	ease list all allergies (such as t N/A st any other important informat	o drugs, foods, pollen or o	others) ch as smoking, pregnancy, alcoho				
	ease list all allergies (such as t N/A	o drugs, foods, pollen or o	others) ch as smoking, pregnancy, alcoho				
	ease list all allergies (such as t N/A st any other important informat	o drugs, foods, pollen or o	others) ch as smoking, pregnancy, alcoho				
	ease list all allergies (such as t N/A st any other important informat	o drugs, foods, pollen or o	others) ch as smoking, pregnancy, alcoho				
Lis	ease list all allergies (such as t N/A st any other important informat No health products until diagnose	o drugs, foods, pollen or ion about the person (suc	others) th as smoking, pregnancy, alcoho				
Lis	ease list all allergies (such as to N/A)  st any other important information in the second se	o drugs, foods, pollen or one of the contract of the person (such that decided the contract of	others) th as smoking, pregnancy, alcoho				
Lis	ease list all allergies (such as t N/A st any other important informat No health products until diagnose	o drugs, foods, pollen or one of the contract of the person (such that decided the contract of	others) th as smoking, pregnancy, alcoho				
Lis	ease list all allergies (such as to N/A)  st any other important information in the second se	o drugs, foods, pollen or one of the contract of the person (such that decided the contract of	others) th as smoking, pregnancy, alcoho				
Lis	ease list all allergies (such as to N/A)  st any other important information in the second se	o drugs, foods, pollen or one of the contract of the person (such that decided the contract of	others) th as smoking, pregnancy, alcoho				
Lis	ease list all allergies (such as to N/A)  st any other important information in the second second in the second in	o drugs, foods, pollen or ion about the person (suc d with Acute Myeloid Leukem cations and medical device Supplements, Entocourt	others) th as smoking, pregnancy, alcoho	ol use, etc.)			

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	N/A				
F.	OTHER (CONCOMITANT) ME	DICAL PRODUCTS		1 of 1	
	Product Name				
	Strength		If Other		
	Therapy Start Date				
	Therapy End Date				
Se	ction E - About the Person Filli	ng Out This Form			
	Last name	(b) (6)			
	First name	(b) (6)			
	Number/Street	(b) (6)			
	City	(b) (6)			
	State/Province	(b) (6)			
	Country	USA			
	ZIP or Postal code	(b) (6)			
	Telephone number	(b) (6)			
	Email address	(b) (6)			
	Today's date	(b) (6)			
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No			
	If you do NOT want your identity disclosed to the manufacturer, place an X in this box:				

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CTU No.: FDA-CDER-CTU-2018-18371 | Department: CFSAN | RCT No.: RCT-128647 | CTU Triage Date: 25-02-2018 | Total Pages

All dates displayed in the report are in EST(GMT-05:00) time zone

	sic Detai	ls		100) 111110 20110					
	ompany U		CDI	ER-CTU	Origi	nating Account	F	FAERS	
Source Medium		MW	O (Drug)	_	ce Form Type	E	E2B XML 3500B		
Priority		Routine							
_	DA Receiv	ed Date	25-I		СТИ	Received Date	2	25-Feb-2018	
C-	TU Triage	Date			Į				
Re	eport Type	}	Spc	ntaneous	Repo	rt Classification	[	Drug	
As	ssign To		Use	r	l				
Us	ser/Group								
Fc	orward to I	Department	V	CDER (CDER-OSE-RS	SS-CT	J@fda.hhs.gov) (E2B)			
						Segradimolgovy (EZB)			
Co	ntact								
_	ase	First Name		Last Name		Email Address		Phone	
Re	eporter	(1) (0)		(1) (2)					
V	1	(b) (6)		(b) (6)					
Se	ction A -	About the Problem							
	What kin	d of problem was it?	D.	Nore burt or had a had side of	fact (incl	iding now or worsening event	iama)		
		ıll that apply)	F			uding new or worsening sympt	oms)		
				Used a product incorrectly which					
				Noticed a problem with the qua			·or		
	Did any	of the following happen?	20			product maker to another mak	<u>er</u>		
		ill that apply)	100	Hospitalization - admitted or st	-	-			
			10.00	Required help to prevent perm	anent ha	rm (for medical devices only)			
			200	Disability or health problem					
				Birth defect					
				_ife-threatening					
				Death	_1 :: -: -:				
	Date the	problem occurred		Other serious/important medica =eb-2018	ai incidei	)T			
T						-   -   -   -   -   -   -   -   -   -			
те		t happened and how					:	ata of this was duet our	
		have a brazilian blowout rom headache back pain					e side ene	ects of this product are	
		·			•	•			
Lis	t any rel	evant tests or <b>l</b> aborate	ory d	ata if you know them	(Inclu	de dates)		=	
Se		About the Products		70. 1.1				1 of 1	
		the product as it on the box, bottle,	Bra:	zilian blowout					
	or packa	ge (Include as many							
	names a	s you see)							

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CTU No.: FDA-CDER-CTU-2018-18371 | Department: CFSAN | RCT No.: RCT-128647 | CTU Triage Date: 25-02-2018 | Total Pages

	Name of the company that makes (or compounds) the product				
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?				
	Expiration date		-		
	Lot number				
	NDC number				
	Strength		If Other		
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Topical	If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?				
	Did the problem return if the person started taking or using the product again?				
	Do you still have the product in	No			
W	case we need to evaluate it?  ny was the person using the pr	oduct? (such as what co	ndition was it supposed to t	reat)	
	Ty was the person doing the pr	- Cader de Mac es	Taken was k supposed to t		
0-		unit-o-			
Se	ction C - About the Medical De Name of medical device	evice			
			-		
	Name of the company that makes the medical device				
Ot	her identifying information (The	e model, cata <b>l</b> og, lot, seri	al, or UDI number, and the	expiration date, if you can	
IOC	cate them)				
	Model #				
	Catalog #				
	Serial #			_	
				_	
	Lot#			_	
	Unique Identifier (UDI) #				
'	Expiry Date			_	

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CTU No.: FDA-CDER-CTU-2018-18371 | Department: CFSAN | RCT No.: RCT-128647 | CTU Triage Date: 25-02-2018 | Total Pages

Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section D - About the Person Who Had the Problem Person's Initials Sex Female Age (specify unit of time for age) 23 Year(s) Date of Birth Weight 56.25 kg(s) Ethnicity (Choose only one) Hispanic/Latino Race (Check all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

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CTU No.: FDA-CDER-CTU-2018-18371 | Department: CFSAN | RCT No.: RCT-128647 | CTU Triage Date: 25-02-2018 | Total Pages

OTHER (CONCOMITANT) M	EDICAL PRODUCTS 1 of 1
Product Name	
Strength	If Other
Therapy Start Date	
Therapy End Date	
ction E - About the Person Fil	ling Out This Form
Last name	(b) (6)
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	USA
ZIP or Postal code	
Telephone number	
Email address	
Today's date	25-Feb-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, place an X in this box:	

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CTU No.: FDA-CDER-CTU-2018-44667 | Department. CFSAN | RCT No.: RCT-154977 | CTU Triage Date: 15-05-2018 | Total Pages

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			and the same of th			
Company Unit	CDER-CTU	Originating Account	FAERS			
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500			
Priority	High					
FDA Received Date	15-May-2018	CTU Received Date	15-May-2018			
CTU Triage Date		CTU Data Entry Date				
Report Type	Spontaneous	Report Classification	Drug			
Assign To	User					
User/Group						
Forward to Department	CDER (CDER	-OSE-RSS-CTU@fda.hhs.gov) (E2B)				
Case Priority	Direct					
to the physical State of the st	Construction of the Constr					
Contact						
Case First Name	Last Name	Email Address	Phone			
Reporter (b) (6)	(6) (6)	(b) (6)	(b) (6)			
		1,000				
A. PATIENT INFORMATION						
Patient Identifier (In Confide						
Age	69 Year(s)	69 Year(s)				
Date of Birth						
Sex	Female					
Weight	49.5 kg(s)	1 0000000				
Ethnicity (Check single best answer)	Not Hispanic/Latino	Not Hispanic/Latino				
Race (Check all that apply)	Asian  American Indian or American Amer					
B. ADVERSE EVENT, PRO	DUCT PROBLEM					
Check all that apply		g., defects/malfunctions) ent Manufacturer of Same Medicine				
Serious	No					
Outcome Attributed to Adver Event (Check all that apply)	Life Threatening Hospitalization - initi	ortant Medical Events) r Damage				
Date of Death	Required Intervention	on to Prevent Permanent Impairment/Damage (De	vices)			

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CTU No.: FDA-CDER-CTU-2018-44667 | Department: CFSAN | RCT No.: RCT-154977 | CTU Triage Date: 15-05-2018 | Total Pages

. 4

	Date of Event	01-May-2018			
	Date of this Report	15-May-2018			
Describe Event, Problem or Product Use Error					

Describe Event, Problem, or Product Use Error: Almost all of my hair has fallen out after using this product for six months.

Relevant <sup>-</sup>	Tests/Laboratory	Data,	Including	Dates

# Other Relevant History, Including Preexisting Medical Conditions

No pre-existing medical conditions, no other hair-care products

# C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Returned to Manufacturer on

PRODUCT(S)			1 of 1	
Suspect	Yes			
Primary?	Yes			
Product Type	Drug/Biologic			
Product Name	Suave keratin infusion heat defense leave-in conditioner			
Strength		If Other		
Manufacturer/Compounder	L Oreal		<u>'</u>	
NDC# or Unique ID	79400 19391 9 no ND			
Is the Product Compounded?	Yes			
Is the Product Over-the-Counter?	Yes			
Event Abated After Use Stopped or Dose Reduced?	No			
Event Reappeared after Reintroduction ?	Doesn't Apply			
g Therapy			1 of 1	
Dose or Amount		If Other		

Drug Therapy 1 of					
	Dose or Amount		If Other		
	Frequency	Other	If Other	weekly	
	Route	Topical	If Other		
	Dosage Form				
	Therapy Start Date	01-Nov-2017			
	Therapy End Date	01-May-2018			
	Therapy Duration		If Other		

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CTU No.: FDA-CDER-CTU-2018-44667 | Department: CFSAN | RCT No.: RCT-154977 | CTU Triage Date: 15-05-2018 | Total Pages

	Therapy Ongoing ?			
	Lot Number	none?		
	Expiration Date			
Dia	agnosis or Reason for Use (inc	dication) 1 of	ī 1	
	hair detangler			
				_
<u>E.</u>	SUSPECT MEDICAL DEVICE			
	Brand Name			
	Common Device Name			
	Procode			
	Manufacturer Name			
	City			_
	State			
	Model #			
	Lot#			_
	Catalog #			_
	Expiration Date Serial #			
				_
	Unique Identifier (UDI) #			
	Operator of Device	Health Professional		
		Lay User/Patient		
	Other	Other		_
	If Implanted, Give Date			_
	If Explanted, Give Date			
	Is this a single-use device that			_
	was reprocessed and reused on a patient?			
	If Yes for the above field,			
	Enter Name and Address of Reprocessor			
E	OTHER (CONCOMITANT) ME	EDICAL PRODUCTS		
-	CONCOMITANT MEDICAL PROD			
G.	REPORTER	1 of	f 1	
, J.	Primary?	Yes		
	Reporter is Patient?			
	Title			
	Last Name	(b) (6)		_
	=4311441110			

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CTU No.: FDA-CDER-CTU-2018-44667 | Department: CFSAN | RCT No.: RCT-154977 | CTU Triage Date: 15-05-2018 | Total Pages

Middle Name			
First Name	(b) (6)		-
Address	(b) (6)		-
City	(b) (6)		
State/Province/Region	(b) (6)		_
Country	USA	If Other	
ZIP/Postal Code	(b) (6)	I	J
Phone	(b) (6)		_
Email	(b) (6)		
Fax			
Reporter Organization			
Department		-	
Reporter Speciality			
Health Professional?	Yes		-
Occupation	Other Health Professional	If Other	
Also Reported to	✓ Manufacturer/Compoun ✓ User Facility ✓ Distributor/Importer	der	J
If you do NOT want your identity disclosed to the manufacturer	No		

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2019-10-25 17:04:14 (GMT) Page 2 of 5 CTU No.: FDA-CDER-CTU-2019-125387 | Department: CFSAN | RCT No.: RCT-639058 | CTU Triage Date: 28-10-2019 | Total Page Form Approved: OMB No. 0910-0291, Expires: 9/30/2018 U.S. Department of Health and Human Services Food and Drug Administration For use by user-facilities, importers, distributors and manufacturers

FORM FDA 3500A (10/15)

for MANDATORY reporting

Page 1 of 4

	FDAI	Ion Onto
UF/Importer F	Report #	
Mfr Report #	US-JNJFOC-20180719747	
,	Seo FRA statement	on reverse.

		11		FDA USE ONI
<b>Note:</b> For date prompts of "dd-mmm-yy abbreviation, and 4-digit year, for exam	/yy" please use 2-digit day, 3-letter month	3. Dose	Frequency	Route Used
	pre, o rodrzoso.	#1		Topical
A. PATIENT INFORMATION				
i. Patient Identifier 2. Age X Yea	ar(s) Month(s) 3. Sex 4. Weight	#2		
(b) (6) 69 We	ek(s) Day(s) X Female			
or Date of Birth	(e.g. 09 Eab 1025)   []  b		nknown give duration) from/	9. Event Abated After Use
In Confidence 09-Sep-	I I Male	to (or best estimate,	or i selesee	Stopped or Dose Reduced
5.a. Ethnicity (Check 5.b. Race (0	Check all that apply)	#1 26-Feb-201	7 -	#1 Yes No X Does
n/n of a ten at annumer	American indian or Alaskan Native	#2		apply
Lionanial ating	African American White	5. Diagnosis for Use	(Indication)	#2 Yes No Does
	lawaiian or Other Pacific Islander	#1 UNKNOWN IN	DICATION	apply
				10. Event Reappeared After
B. ADVERSE EVENT OR PRO	DUCT PROBLEM	#2		Reintroduction?
	Product Problem (e.g., defects/malfunctions)			#1 Yes No X Doesn
2. Outcome Attributed to Adverse Eve		6. Is the Product Compounded ?	7. Is the Product Over- the-Gounter?	apply
Death Include date (dd-mmm-yyy	(y):			#2 Yes No Doesn
Life-threatening	Disability or Permanent Damage	#1 Yes No	#1 Yes No	apply
Hospitalization - initial or prolonged	Congenital Anomaly/Birth Defects	#2 Yes No	#2 Yes No	
Other Serious (Important Medical E	r.	8. Expiration Date (de		
Required Intervention to Prevent Pe	ermanent Impairment/Damage (Devices)	#1	#2	
Date of Event (dd-mmm-yyyy)	4. Date of this Report (dd-mmm-yyyy)	G. ALL MANUFA		
=======================================	25-Oct-2019		anufacturing Site for Devices)	2. Phone Number
5. Describe Eyent or Problem		Name UNJ Consumer	US Cosmetic	732-754-2672
This spontaneous repo	rt received	Address	oc oodiioolo	3. Report Source (Check all that apply)
from a patient of unk gender reporting on s		OCMS		(crock or state depty)
United States via soc		199 Grandvie Skillman, NJ	w Road	Foreign
000311323. The patient's weight,	hairht and	SKIII mair, No	and Study	
medical history were		Email Address	Continue	Literature
	Continued	ngami@its.jn	i.com	Accept
6. Relevant Tests/Laboratory Data, Inc	cluding Dates		-	X Consumer
On an unspecified dat		Compounding Outsourcing	***************************************	Health Professional
physician was consult		4. Date Received by Manufacturer (dd-mmn)	NDA#	User Facility
a biopsy done on her unknown.	scarp, resurts		AMDA#	Company
		27-Sep-201	IND #	Representative
	Continued	6. If IND, Give Protocol#	BLA#	Distributor
7. Other Relevant History, Including P	reexisting Medical Conditions/e.g.		PMAi	Other:
	cohol use, liver/kidney problems, etc.)		510(k)#	
		7. Type of Report		0
		(Check all that apply)	Combination Product Ye	3
		5-day 🗶 30-day		
		7-day Periodic	Pre-1938 Ye	S
C. SUSPECT PRODUCT(S)		10-day ( lollo)(	OTC Ye	15.
. Name, Manufacturer/Compounder,	Strength	15-day X Follow-	up # 5	-
#1 - Name and Strength	#1 - NDC # or Unique ID			
OGX EVER	Continued	9. Manufacturer Report N	lumber 8 Adverse Event Te	emm(s) AL POISONING
#1 - Manufacturer/Compounder	#1 ~ Lot#	20180719747		al poisoning
	unknown	1		128), Chemical
t2 - Name and Strength	#2 - NDC # or Unique ID		27772	Continued
10.	10000000000000000000000000000000000000	E. INITIAL REPO	A	
#2 - Manufacturer/Compounder	#2 - Lot#	1 Name and Address		Continued
	(T) B) (S)	Last Name (b) (6)	First	vame (b) (6)
	Therapy Dates (Exclude treatment of event)	Address (b) (6)		
Concomitant Drugs Not	Reported	city:(b) (6)	State/Provi	nce/Region (b) (6)
		Country: USA	719/19	ostal Code: (b) (6)
			Email: (b)	(6)
ubmission of a sonet does not	constitute an admission that medical	Phone #: 2 Health 3	. Occupation	4. Initial Reporter Also Sent
	distributor, manufacturer or product	Professional?	-	Report to FDA
caused or contributed to the even		☐ Yes 🗓 No	Patlent	Yes No Unk

Date of This Report: 25-Oct-2019

#### B. ADVERSE EVENT OR PRODUCT PROBLEM

#### **B.5 Describe Event or Problem (Cont...)**

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified ) for unknown indication. Concomitant medications were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body. Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product

ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant).

Follow up information was received on 15-JUL-2018. This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018. This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018. This report contains no new regulatory relevant information. No changes were made to the

Additional information was received on 30-AUG-2018. Additional information was received on 30-AUG-2018. This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. This case is a duplicate of 20181013176.

Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the

To: Page 4 of 5 2019-10-25 17:04:14 (GMT) 12679372775 From: Sciformix Corporation

CTU No.: FDA-CDER-CTU-2019-125387 | Department: CFSAN | RCT No.: RCT-639058 | CTU Triage Date: 28-10-2019 | Total Page Sample of 4 Mfr. Report #: 20180719747

Date of This Report: 25-Oct-2019

report.

Follow up information was received on 13-JAN-2019.

This report contains no new regulatory relevant information. No changes were made to the

Additional medically important information was received on 13-JAN-2019. The patient stated that, the product made people sick.

Additional medically important information was received from patient on 01-JUN-2019. On an unspecified date, patient developed formaldehyde poisoning and formaldehyde cancer (chemical poisoning) due to which she was getting sicker and sicker. Patient mentioned that formaldehyde got into her gum skin, eyes, nose, mouth, ears and bones. It was not going away and was affecting her health. The event of chemical poisoning and cancer did not resolve.

Additional medically important information was received from patient on 15-AUG-2019. It was determined that Manufacturer Report Number 20190820522 was a duplicate of this case. All relevant information regarding this case will be submitted under Manufacturer Report Number 20180719747.

The following information was updated and incorporated into the case: The patient demographics were updated. It was reported that the patient got sick due to formaldehyde poisoning of her whole body. She lost her hair and her teeth were removed due to the damage the product caused in her mouth and formaldehyde pockets were found in her gums which were not going away. The patient had not recovered from hair loss and formaldehyde pockets in gums and the outcome of product label issue was unknown.

Additional information was received from patient on 15-JUL-2019. The following information was updated and incorporated into the case: The reporter details were updated.

Additional information received from consumer on 27-SEP-2019. Upon review the following Additional information received from consumer on 27-SEP-2019. Upon review the following correction were done: On an unspecified date, the patient experienced redness on skin, blurriness and watering of the eyes, sores in mouth, infection of ears, nose, throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, snapping and rotting out of product from whole body (application site reaction), damaged skin and bones with swelling pain.

The patient had not recovered from research nose throat and skin on whole body, swelling of body. sores in mouth, infection of ears, nose throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, damaged skin and bones with swelling pain and the outcome of snapping and rotting out of product from whole body (application site reaction) was unknown.

The DC/RC was updated from unknown to not applicable for (chemical poisoning, formaldehyde pockets in gums, hair, bumps on body and cracks in head and product snapping and rotting out of whole body). The DC/RC captured as unknown for mouth sores. The event of product

quality complaint removed from case.
This case is duplicate of 20190939051, 20190623129, 20180125792, 20180902554, 20181202118, 20181217921, 20181113853, 20190609048, 20190821504, 20180133420, 20181117366, 20181216775, 20190822079, 20181013667, 20190626249, 20190701083 and 20180102688.

# Company Remarks:

#### B.6 Relevant Tests/Laboratory Data, Including Dates (Cont...)

#### Lab Result:

Test date Test result Normal value Classification Test name

BIOPSY unknown

(Biopsy)

# C. SUSPECT PRODUCT(S) (Cont...)

Seq No. C.1 Suspect Product	:1 :OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z
C.9 Dechallenge	:2) N/A :3) UNK :4) UNK :5) UNK :6) UNK

C.10 Rechallenge :2) :3) N/A

UNK :4) UNK

UNK

To: Page 5 of 5 2019-10-25 17:04:14 (GMT) 12679372775 From: Sciformix Corporation

Date of This Report: 25-Oct-2019

:6) UNK

## E. INITIAL REPORTER (Cont...)

State: Rhode Island

Email: totalonipper@gmail.com

## G. ALL MANUFACTURERS

#### G.1 Contact Office: Name/Address (and Manufacturing Site for Devices)

United States of America (Printing Unit)

#### **G.8 Adverse Event Term(s)**

- 1) CHEMICAL POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
  2) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))
  3) HAIR LOSS (Application site alopecia (10059046), Application site alopecia (10059046))
  4) MOUTH SORES (Sores mouth (10049318), Stomatitis (10042128))
  5) BUMPS ALL OVER BODY (Application site papules (10049043), Application site papules
- (10049043))
  6) CRACKS IN HEAD AND PRODUCT SNAPPING AND ROTTING OUT OF WHOLE BODY (Application site reaction (10003055), Application site reaction (10003055))

# CTU No.: FDA-CDER-CTU-2018-70116 | Department: CFSAN | RCT No.: RCT-180449 | CTU Triage Date: 30-07-2018 | Total Pages

U.S. Department of Health and Human Services Food and Drug Administration

# **MEDWATCH**

3500A Facsimile

JNJ Consumer US Cosmetic

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

	FDA Fecsimile Approval: 01/30/2007
Minsons US-JNJFOC-21	0180719747
UF/Intpotter report #	
	FDA usp only

Page 1 of 3

A DATIENT	NFORMATION			C. SUSPECT F	PRODUCT(S)	1	
1. Patient Identifier		3. Sex	4. Weight	1. Name (Give labelet	d strength & mfr/la	baler)	
(b) (6)	of Event:	☐ Female	UNK ibs				L KERATIN THERAPY
(-71-7	or Unknow	n Male	OF OF	#2 CONB 1302	(GGX EVER	STRAIGHT	ENING: Shampoo
In confidence	of Birth: ??/??	/???? UNK	UNK kgs	2. Dose, Frequency 8	Banta Hand	In Theorem	5.1
B. ADVERSE	<b>EVENT OR PROD</b>	DUCT PROBLEM			Route Usea	(or best estim	
1. X Adverse Event	t and/or X Product	Problem (e.g., defects/s	nalfunctions)	#1 Topical		#1 22/2	?/????-??/??/????
2. Outcomes Attribu	uted to Adverse Event (	(Check all that apply)		#2		#2	
Death(mm/dd	divay) Di	isability or Permanent Da	mage	4. Diagnosis for Use	(Indication)		5. Event Abated After Use
Life-threatening		ongenital Anomaly/Birth I	Defect	#1 PRODUCT USE		OF IN	Stopped or Dose Reduced?
∭Hospitalization - i	nitial or prolonged X Ot	ther Serious (important Me	dical Events)	INDICATION		Ŧ	*1 Yes No Doesn't UNK Apply
Required Interver	ntion to Prevent Permanen	nt Impairment/Damage(D	evices)	#2		ź	2 Yes No Doesn't
3. Date of Event (cm		Date of This Report (ave	<i>(аа</i> <b>ўу</b> ууў	6. Lot#	7. Exp. Date		Apply
??/??/???? 5. Describe Event o		7/27/2018		#1 unknown	- #1 ??/??/	????	3. Event Reappeared After Reintroduction?
	neous report rec	ceived from a p	patient	#2	#2	#	#1 Yes No Doesn't
	age and gender s			9. NDC# or Unique ID			UNK Apply  #2 Yes No Doesn't
United State	es via social me	edia: 00031132	3,			*	Apply
The patient	's weight, heigh	ht and medical	history	10. Concomitant Med	lical Products and	d Therapy Da	ates (Exclude treatment of event)
were unknow	n.			No Concomitan	t Products	Reporte	d
<u> </u>	-161-3 3-4- 45.			D. SUSPECT N	AEDICAL DE	MOE	
	cified date, the RAIGHTENING BRAI			1. Brand Name	IEDICAL DE	VICE	
	130Z (EVER STR						
	DITIONER 386) (to			2. Common Device N	ame		
	napecified ) for medications	r unknown indic	ation.				
Walter Court of the Court of th	100040000000000000000000000000000000000			3. Manufacturer Nam	e, City and State		
			(Cont.)	4.Model#	Lot#		5.Operator of Device
	aboratory Data, Including	-		1			
No Relevant	Test/Laboratory	Data Reported		Catalog #	Expiration	Date (mm/okl/yyy	
							Lay User/Patient Other
				Serial#	Other#		Cirici
				6.lf Implanted, Give D	Pate (mm/dd/www)	7.lf Expla	anted, Give Date (mm/dd/yyyy)
				8.Is this a Single-use		Reprocessed	d and Reused on a Patient?
				9.If Yes to Item No. 8.		Address of I	Reprocessor
7 Other Relevant Hi	story, Including Preexist	ing Medical Conditions	te n. allemies				
	oking and alcohol use, hep						
				10. Device Available	for Evaluation?	Do not send to I	FDA)
Mo Dalamant	History Repor	rtad		Yes No		Manufacturer	on:
NO RELEVANC	niacory Repor	LCEU		11. Concomitant Med	ical Products and	d Therapy Da	(molokiyyy) ites (Exclude treatment of Event)
						, , ,	
				E. INITIAL REP	PORTER		
				1. Name & Address		Phone #	
				(p)(6)			
				THITMES COAMS			
				UNITED STATES	2		
	of report does not con		that	2. Health Professions	1? 3. Occupa	tion	4.Initial Reporter Also Sent
construction and the second	onnel, user facility, important or product caused or	Market Committee	vent.	Yes X	No Unknown		Report to FDA
				1	1		Yes No X Unk

To: Page 3 of 4 2018-07-27 06:54:53 (GMT) 12679372775 From: Sciformix Corporation

CTU No.: FDA-CDER-CTU-2018-70116 | Department: CFSAN | RCT No.: RCT-180449 | CTU Triage Date: 30-07-2018 | Total Pages

: 3

# **MEDWATCH**

3500A Facsimile (Continued)

JNJ Consum	er US	Cosmetic
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U.S.	DEPAR	DA USE DE HEAL		MAN SE	:RVIC	ES
		e • Foo				
				FDA	les f	mi

Page 2 of 3

F. FOR USE B	Y USER F	ACILITY/IMPORT	ER (Devices Only)	H. DEVICE MANUFACTURERS	ONLY
1. Check One		2. UF/Importer F		1. Type of Reportable Event	2. If Follow-up, What Type?
User Facility	Importer			Death	Correction
3. User Facility or In	nporter Name/	Address		Serious Injury	Additional Information
				Malfunction	Response to FDA Request
				Other:	Device Evaluation
				3. Device Evaluated by Manufacturer?	4.Device Manufacture Date
4. Contact Person		5. Phon	e Number	Not Returned to Manufacturer	(Introlyyyy)
6.Date User Facility	or Importer	7.Type of Report	8.Date of This Report	Yes Evaluation Summary Attached	
Became Aware of		Initial	(mm/dd/yyyy)	No (Attach page to explain why not) or	5. Labeled for Single Use?
(mm/dd/yyyy)		Follow-up#		provide code:	Yes No
9.Approximate		oblem Codes <i>(Refer to co</i>	ding manual)	6. Evaluation Codes (Refer to coding manua	<i>I</i>
Age of Device	Patient Code	-	-	Method -	, , ,
	Device Code	-	<b>-</b>	Netriod	
11. Report Sent to F	Code L	12. Location Where Ever	nt Occurred	Results -	
☐ Yes		Hospital	Outpatient Diagnostic Facility		
☐ No	nm/did/yyyy)	Home	Diagnostic Laurity	Conclusions	
13. Report Sent to Man	ufacturer?	Nursing Home Outpatient	Ambulatory Surgical	7. If Remedial Action Initiated, 8.	Usage of Device
☐ Yes		Treatment	Facility	Check Type	Initial Use of Device
No (m	m/dd/ <b>yyy</b> y)	Facility		Recall Notification	Reuse
		Other:	(Specify)	Repair Inspection	Unknown
14. Manufacturer Na	ame/Address			Replace Patient Monitoring	If action reported to FDA under
				Relabeling Modification/ 9. Adjustment	21 USC 360i(f), list correction/
				Other:	removal reporting number:
				10 Additional Manufacturer Narrative	and/or 11. Corrected Data
G. ALL MANU	EACTUDE	- DC			30.
		(and Manufacturing	2.Phone Number		
Site for Devices)	iallie: Auul 655	land manuracturing	1		
Thir Gamana	- FIO (3		-6094559402		
JNJ Consume: 199 Grandvi:		metro	3.Report Source (Check all that apply)		
Skillman	on mona		Foreign		
NJ			Study		
UNITED STATI	ES		Literature		
			X Consumer		
4.Date Received by (mm/dd/yyyy)	Manufacturer		Health Professional		
07/15/2018		(A)NDA#	User Facility		
6. If IND, Give Proto	col#	IND#	Company Representative		
		STN#	Distributor		
7. Type of Report (C)	heck all that apply!	PM/V	Other:		
	30-day	510(K)#			
7-day	Periodic	Combination Yes			
10-day X	Initial	Pre-1938 Yes			
	Follow-up#	OTC Product Yes			
A 14	4 11		4		
9. Manufacturer Rep	ort Number	8. Adverse Event Term 1) CHEMICAL POI	AND The second control of the second		
JNJF0C-2018	0710747		(Cant )		

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information, Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to.

Department of Health and Human Services Food and Drug Administration - MedWatch 10903 New Hampshire Avenue Bulkting 22, Mail Stop 4447 Silver Spring, MD 20993-0002 OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

To: Page 4 of 4

2018-07-27 06:54:53 (GMT)

12679372775 From: Sciformix Corporation

CTU No.: FDA-CDER-CTU-2018-70116 | Department: CFSAN | RCT No.: RCT-180449 | CTU Triage Date: 30-07-2018 | Total Pages : 3

> JNJ Consumer US Cosmetic 199 Grandview Road Skillman

Date of this report: 07/27/2018

Mfr. report#: US-JNJFOC-20180719747

Page 3 of 3

Continuation Sheet for FDA-3500A Form

#### B5. Describe Event or Problem (Cont...)

were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.

Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant).

Senders Comments/Medical Assessment: .

#### G8. Adverse Event Term (Cont...)

2) PRODUCT FORMULATION ISSUE

U.S. Department of Health and Human Services Food and Drug Administration

**MEDWATCH** 

manufacturer or product caused or contributed to the event.

For use by user-facilities, distributors and manufacturers for

JNJ Consumer US Cosmetic

MANDATORY reporting

FDA Facelmile Approvat: 01/30/2007	_
JS-JNJFOC-20180719747	
iFrienderior report #	
FDA uso of	4

Yes No X Unk

Page 1 of 4

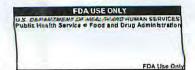
A PATIENT I	NFORMATION		V = 0 14	C. SUSPECT	PRODUCT(S)	
1. Patient Identifier	2. Age at Time	3. Sex	4. Weight	1. Name (Give labele #1 OCX EVER	ed strength & mfr/labeler)	PRAZIL KERATIN THERAPY
(b) (6)	of Event:	X Female	UNK bs	COND 130Z	(OGX EVER STR	AIGHTENING) Shampoo
	Date	Male Male	or	#2		
In confidence	of Birth: ??/??	/2333	IJNN kgs	2. Dose, Frequency	& Route Used 3	. Therapy Dales (Municom, gov director) from
	EVENT OR PRO			#1 Topical		or bost estimotes 1 02/26/2017-22/22/2222
1. X Adverse Even		Problem (e.g., defeats/n	nalfunctions)	#2		2
2. Outcomes Attrib	uted to Adverse Event		51000	5.		
Death(inm/di	d(MM)	isability or Permanent Da		4. Diagnosis for Us	The state of the s	5. Event Abated After Use Stopped or Dose Reduced?
Life-threatening	- Annual -	ongenital Anomaly/Birth I		#1 PRODUCT US INDICATION	ED FOR UNKNOWN	#1 Yes No Doesn'
Hospitalization -		ther Serious (Important Me				#2 Yes No Doesn
_	ention to Prevent Permane	Date of This Report		#2 6. Lot#	7. Exp. Date	Apply
3. Date of Event (m)		9/20/2018	100377717	#1 unknown	#1 ??/??/??	?? 8. Event Reappeared After Reintroduction?
5 Describs Event	or Problem			#2	#2	#1 Yes No Doesn'
This sponta	neous report re age and gender	ceived from a	elf from	9. NDC# or Unique	ID	UNK Apply
United Stat	es via social m	edia: 00031132	3.			#2 Yes No Doesn Apply
	's weight, heig	bt and medical	history	10. Concomitant M	edical Products and Th	erapy Dates (Exclude treatment of event)
were unknow	m.	mr and medical		No Concomita	ant Products Re	eported
	cified date, th	o sationt star	ted using	D. SUSPECT	MEDICAL DEVI	CE
DOX EVER ST	PAIGHTENING PRA	ZIL KERATIN TH	ERAPY	1. Brand Name		
CONDITIONER	1302 (EVER STE	MAIGHT BRAZILIA	N KERATIN	2. Common Device	Name	
THERAPY CON	DITIONER 386) (1 inspecified ) for	opical, dose a	cat_on.	100000000000000000000000000000000000000		
Concomitant	medications			3. Manufacturer Na	me. City and State	
-				100		
			10.00			
C Defenses Freds (	Laboratory Data, Includi	na Dates	(Cont.)	4.Model#	Lot#	5.Operator of Device
	Test/Laborator		d.	Catalog #	Expiration Date	Health Professional
	3.42 3.50 0.00			Catalog #		Lay User/Palient
				Serlal #	Other #	Other
						7.If Explanted, Give Date (mm/co/yyy)
				6.H Implanted, Give	e Date (w-wastyy)	7.11 Expirition, Give Date (missyy)
				8.1s this a Single-u	se Device that was Rep	rocessed and Reused on a Patient?
					No . 8, Enter Name and Add	drace of Banracassar
				S.II Yes to Remited	o, Emer Hame and Ad	arasa si Neproseesi
7.Other Relevant H	History, Including Pression making and alcohol use, he	eting Medical Condition	s(e.g., allergies, etc.)			
				10. Device Availab	le for Evaluation? (Do n	
No Relevan	t History Repo	orted				(איניייינים)
				11. Concomitant M	ledical Products and Tr	nerapy Dates (Exclude treatment of Event)
				E. INITIAL RI	EPORTER	
				1. Name & Address		ne#
				(h) (6	1	
				(0) (0	1	
				UNITED STAT	2.5	3
				1		
	of report does not co		n that	2. Health Professio	onai? 3. Occupation	4.Initial Reporter Also S
	sonnel, user facility, in or or product caused of		event.	Yes X	그 얼마 아이를 보고 있다면 하는데 하는데 하는데 되었다.	Report to FDA

CTU No.: FDA-CDER-CTU-2018-89122 | Department: CFSAN | RCT No.: RCT-200316 | CTU Triage Date: 27-09-2018 | Total Pages

JNJ Consumer US Cosmetic

# **MEDWATCH**

3500A Facsimile (Continued)



Page 2 of 4

F. FOR USE BY USER FACILITY/IMPOR	TER (Devices Only)	H. DEVICE MANUFACTURERS	ONLY
	Report Number	1. Type of Reportable Event	2. If Follow-up, What Type?
User Facility Importer		Death	Correction
3. User Facility or importer Name/Address		Serious Injury	Additional Information
and the second of the second o		Malfunction	Response to FDA Request
		Olher:	Device Evaluation
	1		
		3. Device Evaluated by Manufacturer?	4.Device Manufacture Date (mm/yyyy)
4. Contact Person 5. Pho	one Number	Not Returned to Manufacturer	
	In not set while named	Yes Evaluation Summary Attached	
6.Date User Facility or Importer 7.Type of Report Became Aware of Event   Initial	8.Date of This Report	No (Altach page to explain why not) or	5. Labeled for Single Use?
mm/dryyy)   Follow-up#		provide code:	Yes No
	rading manual)		
Age of Device Patient		6. Evaluation Codes (Refer to coding manual	91)
Code		Method -	4
Device Code -			
11. Report Sent to FDA? 12. Location Where Ev		Results -	-
Yes Hospital	Outpatient Diagnostic Facility		
No (mm/ad/yyy)1 Home	Diagnostic Facility	Conclusions	
Nursing Home	Ambulatory Surgical		
13. Report Sent to Manufacturer? Outpatient Treatment	Facility	7. If Remedial Action Initiated, 8 Check Type	. Usage of Device Initial Use of Device
Yes Facility		Recall Notification	
☐ No ☐ Other:		Repair Inspection	Reuse
	(Specify)	Replace Patient Monitoring	Unknown
14. Manufacturer Name/Address		The state of the s	. If action reported to FDA under
G. ALL MANUFACTURERS		10 Additional Manufacturer Narrative	and/or 11. Corrected Data
Contact Office - NamelAddress (and Manufacturing Site for Devices)	2.Phone Number		
JNJ Consumer US Cosmetic	-6094559402 3.Report Source		
199 Grandview Road	(Check of that apply)		
Skillman	Foreign	V	
NJ	Study		
UNITED STATES	Literature		
	X Consumer		
4.Date Received by Manufacturer 5.	Health Professional		
(A)NDA#	User Facility		
08/30/2018 IND#	Company		
	Representative		
7. Type of Report (Check all thet apply)	Distributor		
DE-day PMA/	Other:		
7-day Degradic	-		
10-day Initial Product Yes	·		
=			
15-day X Follow-up # Pre-1938 Yes			
1			
9. Manufacturer Report Number   8. Adverse Event Ter	m(s)		
US- 1) CHEMICAL FO	TO STATE AND ADDRESS OF THE PARTY OF THE PAR		
JNJF0C-20180719747	(Cont.)		

The public reporting burden for this collection of information has been estimated to average 66 immulas soll response, including the time for reviewing instructions, searching concling data courses, gathering and maintaining the data modest, and completing and reviewing the collection of information, Send comments regarding this burden estimate or any other aspect of this collection of information, including suppositions for reducing this burden to

Department of Health and Human Services Food and Diug Administration - MedWatch 19903 New Hampshire Avenus Building 22, Mail Step 4447 Silker Spring, MD 20993-0002 Please DO NOT RETURN into form to this address.

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CTU No.: FDA-CDER-CTU-2018-89122 | Department: CFSAN | RCT No.: RCT-200316 | CTU Triage Date: 27-09-2018 | Total Pages

JNJ Consumer US Cosmalic 199 Grandview Road Skillman Mfr. reports: US-JNJF0C-20180719747 Date of this report: 09/20/2018

Continuation Sheet for FDA-3500A Form

Page 3 of 4

B5. Describe Event or Problem (Cont...)
were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.

Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 1302 (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant). Follow up information was received on 15-JUL-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Additional information was received on 30-AUG-2018.

This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to light the poison every day, The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171106730, 20171120957, 20180324707,

To: Page 5 of 5

2018-09-21 03:38:49 (GMT)

12679372775 From: Scitormix Corporation

CTU No.: FDA-CDER-CTU-2018-89122 | Department: CFSAN | RCT No.: RCT-200316 | CTU Triage Date: 27-09-2018 | Total Pages

JNJ Consumer US Cosmelic 199 Grandview Road

Mir. report#: US-JNJFOC-20180719747 Date of this report: 09/20/2018

Continuation Sheet for FDA-3500A Form

Page 4 of 4

20180828488, 20180901076, 20180903071 and 20180724202.

Senders Comments/Medical Assessment: .

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

Lab Result:

Test Name BIOPSY

??/??/????

Test Result

unknown

Normal High

Normal Low

G8. Adverse Event Term (Cont...)

2) PRODUCT FORMULATION ISSUE

CTU No.: FDA-CDER-CTU-2019-10893 | Department: CFSAN | RCT No.: RCT-250117 | CTU Triage Date: 30-01-2019 | Total Reges | 100 |

JNJ Consumer US Cosmetic

U.S. Department of Health and Human Services Food and Drug Administration

# **MEDWATCH**

3500A Facsimile

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

	Levis Lucinicasa selbuneas: n sensenno.
Mir roport #	
US-JNJFOC-	20180719747
DF4mconor report ≠	
	FDA (as only

Page 1 of 4

2. Outcomes Attributed to Adverse Event (Check sil that spply)  Death:	00			
of Event: or 68 Years Date of Birth: ??/??/???  B. ADVERSE EVENT OR PRODUCT PROBLEM  1.   Adverse Event and/or   Product Problem (e.g., defects/maltunctions)  1.   Disability or Permanent Damage   Disability or Permanent Damage   Disability or Permanent Damage   Disability or Permanent Damage   Product Problem   Proportial Anomaly/Birth Defect   Proportial Anomaly/Birth Defect	00			
Date of Birth: ??/??????   Date of Birth: ??/??????????????????????????????????				
B. ADVERSE EVENT OR PRODUCT PROBLEM  1.X Adverse Event and/or X Product Problem (e.g., defects/mailtanctions)  2. Outcomes Attributed to Adverse Event (Check all that spply)  Death:	is about and the control			
B. ADVERSE EVENT OR PRODUCT PROBLEM  1. X Adverse Event and/or X Product Problem (e.g., defects/maltunctions)  2. Outcomes Attributed to Adverse Event (Check sill that apply)  Death:	is about a local disease by			
1. X Adverse Event and/or X Product Problem (e.g., defects/mallunctions) 2. Outcomes Attributed to Adverse Event (Check all that spply)  Death:	a display frome			
2. Outcomes Attributed to Adverse Event (Check ell that apply)  Death: Unanticatypy)  Death: (Inmicatypy)  Uide-threatening Congenital Anomaly/Birth Defect Haspitalization - initial or prolonged X Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage(Devices)  3. Date of Event (Immicatypy) 3. Describe Event or Problem  This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.  The patient's weight, height and medical history were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING EPAZIL KEPATIN THERAPY CONDITIONER 1302 (EVER STRAIGHT ERAPTIN THERAPY CONDITIO	/????			
Death:   Disability or Permanent Damage   Life-threatening   Congenital Anomaly/Birth Defect   Hospitalization - initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization - initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization - initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization   Initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization   Initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization   Initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization   Initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization   Initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization   Initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization   Initial or prolonged   Medical Events   Hospitalization   Initial or prolonged   X Other Serious (Important Medical Events)   Hospitalization   Initial or prolonged   No Concomitant Medical Products   Hospitalization   Initial or prolonged   No Concomitant Medical Products and Therapy Dates (Exclude Investment No Concomitant Products Reported   Initial Octoor   Initial or prolonged   No Concomitant Products   Initial Octoor   Initial Octoor				
Life-threatening				
Hospitalization - initial or prolonged   X Other Serious (Important Medical Eventa)				
Haspitalization - initial or prolonged   X   Other Serious (tapportant Medical Events)     Required Intervention to Prevent Permanent Impairment/Damage(Devices)     3. Date of Event   tambet/pypy    4. Date of This Report   tambet/pypy      7. Exp. Date				
3. Date of Event (permoddy)999  72/72/727  101/25/2019  5. Describe Event or Problem  This apontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.  The patient's weight, height and medical history were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 1302 (EVER STRAIGHTENING BR	Apply			
77/77/77?  5. Describe Event or Problem  This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.  The patient's weight, height and medical history were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING BFAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT ERAZILIAN KERATIN THERAPY CONDITIONER 130Z (EVER	Doesn't			
This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.  The patient's weight, height and medical history were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING BFAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT ERAZILIAN KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDI	Apply			
This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.  The patient's weight, height and medical history were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 1302 (EVER STRAIGHT PRAZILIAN KERATIN THERAPY CONDI	After			
This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.  The patient's weight, height and medical history were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING BPAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT PRAZILIAN KERATIN THERAPY CONDI	Doesn't			
of unknown age and gender reporting on self from United States via social media: 000311323.  The patient's weight, height and medical history were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT PRAZILIAN KERATIN THE	Apply			
The patient's weight, height and medical history were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT PRAZILIAN KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGH				
The patient's weight, height and medical history were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING BPAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT PRAZILIAN KERATIN THERAPY CONDITIONER 2. Common Device Name 2. Common Device Name 386) (topical, dose and frequency unspecified)	Apply			
were unknown.  On an unspecified date, the patient started using OGX EVER STRAIGHTENING BPAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified)  3.Manufacturer Name, City and State	OI GARLET			
On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT PRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified)  3. Manufacturer Name, City and State				
On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT ERAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified)  1. Brand Name  2. Common Device Name  3. Manufacturer Name, City and State				
using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT ERAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified) 3.Manufacturer Name, City and State				
BRAZILIAN KERATIN THERAPY CONDITIONER  386) (topical, dose and frequency unspecified )  3. Manufacturer Name, City and State				
386) (topical, dose and frequency unspecified )  3. Manufacturer Name, City and State				
for unknown indication. Concomitant medications	2 Manufactures Name City and State			
202 UNKNOWN ZHOZEGEZONI CONCONIZECTO				
(Cont.) 4.Model# Lot# 5.Operator of De	vice			
	of a set			
Catalog # Expiration Date Immibility   -				
Lay User/Pali	ent			
Serial # Other # Other				
R.Antonian Agrantian Company of the				
6.If Implanted, Give Date (mmourph) 7.If Explanted, Give Date (mm	161255557			
8.1s this a Single-use Device that was Reprocessed and Reused on a P	atlent7			
Yes No				
9.ff Yes to Item No. 8, Enter Name and Address of Reprocessor				
7.Other Relevant History, Including Preexisting Medical Conditions(e.g., allergies.				
race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)				
No Relevant History Reported 10. Device Available for Evaluation? (Do not send to FDA)				
Yes No Returned to Manufacturer on:	Yes No Returned to Manufacturer on:			
11. Concomitant Medical Products and Therapy Dates (Exclude treelment	of Eventy			
E. INITIAL REPORTER				
1. Name & Address Phone #				
(b) (6)				
UNITED STATES				
the state of the second size in that				
Submission of report does not constitute an admission that medical personnel, user facility, Importer, distributor,  2. Health Professional?  3. Occupation  4.Initial Report to FD				
medical personnel, user facility, importer, distributed, manufacturer or product caused or contributed to the event.  Yes X No Unknown Yes				

CTU No.: FDA-CDER-CTU-2019-10893 | Department: CFSAN | RCT No.: RCT-250117 | CTU Triage Date: 30-01-2019 | Total Pages

JNJ Consumer US Cosmetic

# **MEDWATCH**

3500A Facsimile (Continued)

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PUBLIC Health Service • Food and Drug Administration

Page 2 of 4

FDA Use Only

F. FOR USE BY USER FA	ACILITY/IMPORTI	ER (Devices Only)	H. DEVICE MANUFACTURERS	ONLY
1, Check One	2. UF/Importer R		1. Type of Reportable Event	2. If Follow-up, What Type?
User Facility Importer			☐ Death	Correction
3. User Facility or Importer Namel	Address		Serious Injury	Additional Information
The state of the s			Malfunction	Response to FDA Request
			Other:	Device Evaluation
			3. Device Evaluated by Manufacturer?	4.Device Manufacture Date
	Is Phon	e Number	Not Returned to Manufacturer	(mm/yyyy)
4. Contact Person	5. Phon	e Number		
6.Date User Facility or Importer	7.Type of Report	8.Date of This Report	Yes Evaluation Summary Attached	5. Labeled for Single Use?
Became Aware of Event	[ Initial	(πανασίνγγγ)	No (Attach page to explain why not) or provide code:	
tmm/d/yyyy)	Follow-up #			Yes No
	blem Codes/Refer to coo	ling manual)	6. Evaluation Codes (Refer to coding manual	0
Age of Device Patient Code		•	Method	
Davico	1-1		, serios	
11. Report Sent to FDA?	12. Location Where Ever	t Occurred	Results -	-
	Hospital	Outpatient		
Yes	Home	Diagnostic Facility	Conclusions -	
	Nursing Home	Ambulatory Surgical	7 K Damadial Aplica Initiated In	Usage of Device
13. Report Sent to Manufacturer?	Outpatient Treatment	Facility	7. If Remedial Action Initiated, 8. Check Type	Initial Use of Device
Yes	Facility		Recall Notification	
□ No	Other:		Repair Inspection	Reuse
N. M. Maria	P A CANAL	(Specify)	Replace Patient Monitoring	Unknown
14. Manufacturer Name/Address			Relabeling Modification/ 9.	If action reported to FDA under
			Adjustment	21 USC 360I(f), list correction/ removal reporting number:
			Other:	Tomoral Topo, Ing.
			10 Additional Manufacturer Narrative	and/or 11. Corrected Data
		一		
G. ALL MANUFACTURE				
1. Contact Office - NamelAddress Site for Devices)	(and Manufacturing	2.Phone Number		
Site for Devices)		-60945594	V	
JNJ Consumer US Co:	smetic	02		
199 Grandview Road		3.Report Source		
Skillman		(Check all that apply)		
UNITED STATES		Foreign Study		
ONITED STRING		Literature		
		X Consumer	3 18 1	
4.Date Received by Manufacturer		Health Professional		
01/13/2019	(A)NDA #	User Facility		
6. If IND, Give Protocol #	IND#	Company		
	STN#	Representative		
7. Type of Report (Chack et that apply)		Distributor		
5-day X 30-day	PMA/ 510(K)#	Other:		
7-day Periodic	to the same of the			
	Product Yes			
	Pre-1938 Yes			
15-day X Follow-up#	OTC Product Yes			
2				
9. Manufacturer Report Number	8. Adverse Event Term			
US-JNJFOC-20180719747	1) CHEMICAL PO			
2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		(Cont.)		

The public reporting burden for this collection of information has been estimated to average 66 remulas per response, including the time for reviewing instructions, searching existing date sources, gathering and maintaining the date mooded, and complating and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to.

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CTU No.: FDA-CDER-CTU-2019-10893 | Department: CFSAN | RCT No.: RCT-250117 | CTU Triage Date: 30-01-2019 | Total Pages

JNJ Consumer US Cosmetic 199 Grandview Road Skillman

Continuation Sheet for FDA-3500A Form

Page 3 of 4

Mfr. report#: US-JNJFOC-20180719747 Date of this report: 01/25/2019

B5. Describe Event or Problem (Cont...) were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.

Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 1302 (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant). Follow up information was received on 15-JUL-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Additional information was received on 30-AUG-2018.

This report concerns a 68 year old female patient, On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 1302 (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was

CTU No.: FDA-CDER-CTU-2019-10893 | Department: CFSAN | RCT No.: RCT-250117 | CTU Triage Date: 30-01-2019 | Total Pages

JNJ Consumer US Cosmelic 199 Grandview Road Skillman

Continuation Sheet for FDA-3500A Form

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Mfr. reports: US-JNJFOC-20180719747 Date of this report: 01/25/2019

#### B5. Describe Event or Problem (Cont...)

unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information.

This case is a duplicate of 20181013176. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 13-JAN-2019.

This report contains no new regulatory relevant information. No changes were made to the report. Additional medically important information was received on 13-JAN-2019.

The patient stated that, the product made people sick. Senders Comments/Medical Assessment: ...

## B.6 Relevant Tests/Laboratory Data, Including Dates (Cont...)

Lab Result: Test Name

BIOPSY

Test Date ??/??/????

Doknown

Normal High

Normal Low

# G8. Adverse Event Term (Cont...)

2) PRODUCT FORMULATION ISSUE

CTU No.: FDA-CDER-CTU-2019-09792 | Department: CFSAN | RCT No.: RCT-408814 | CTU Triage Date: 14-06-2019 | Total Pages

JNJ Consumer US Cosmetic

U.S. Department of Health and Human Services Food and Drug Administration

# **MEDWATCH**

3500A Facsimile

For use by user-facilities, distributors and manufacturers for

MANDATORY reporting

FDA Facsimite Approva	4: 01/2012007
Mirropode	
US-JNJFOC-20180719747	
UF/Importer report #	
	FDA use only

Page 1 of 4

A. PATIENT IN	NEORMATION			C. SUSPECT PR	ODUCT(S)		
	2. Age at Time	3. Sex 4	. Weight	1. Name (Give labeled s	trength & mfr/labe	ler)	
(b) (6) of Event: X Female bs			lbs				L KERATIN THERAPY
			or:	COND 1302 (OGX EVER STRATGHTENING) Shampoo			
In confidence	Date of Birth: ??/??/	3333 2	JNK kgs	#2	***************************************	·	
B ADVERSE	EVENT OR PROD	LICT PROBLEM		2. Dose, Frequency & R	oute Used	3. Therapy (or best estima	/ Dates   If unknown, give duration) from to
	and/or X Product F		functions)	#1Topical		#1 02/26	6/2017-??/??/????
	ted to Adverse Event (0			#2		#2	
Death:	_ `	ability or Permanent Dama	100			130.500	
(min/da	(VYVY)			4. Diagnosis for Use (in		l e	Event Abated After Use
Life-threatening		ngenital Anomaly/Birth Def		#1 PRODUCT USED	FOR UNKNOW		topped or Dose Reduced?
Mospitalization - in	. • • • • • • • • • • • • • • • • • • •	er Serious (Impodam Medica		INDICATION			UNK Apply
	tion to Prevent Permanent			#2		#2	Yes No Doesn't
3. Date of Event (mm) ??/??/????		ate of This Report (movida) /12/2019	irrr)	6. Lot #	7. Exp. Date	_	Apply
5. Describe Event or		/12/2015		#1 unknown	#1 ??/??/?		Event Reappeared After eintroduction?
				#2	#2		1 Yes No Doesn't
_	neous report rec	-		9. NDC# or Unique ID	<b></b>		UNK Apply
	age and gender r as via social me		f from			#:	2 Yes No Doesn't
United State	es via sociai me	aru: nonzrrzez.		10 Concomitant Medica	al Products and 1	herany Dat	Apply  (Exclude treatment of event)
The patient'	's weight, heigh	t and medical h	istory	No Concomitan			
were unknown						1	
Marine etteratur enementetatulitarina				D. SUSPECT ME	DICAL DEV	ICE	
	cified date, the			1. Brand Name			
	ÆR STRAIGHTENIN DITIONER 1302 (E		N.				
TANDER - CHARLES AND STATE STATES OF	ERATIN THERAPY C			2, Common Device Name			
The state of the s	, dose and freq		ed)	3. Manufacturer Name.	City and State		
for unknown	indication. Con	comitant medica	tions	o, managed or came;	only and otals		
			(Cont.)	4.Model#	Lot#		5.Operator of Device
6. Relevant Tests/La	boratory Data, Including	Dates					Health Professional
				Catalog #	Expiration Da	ite (mm/ódáyyyy	Lay User/Patient
				A 1.14	011 #		Other
				Serial #	Other #		
			-	6.ff Implanted, Give Dat	O formalistical	7 If Evnlor	nted, Give Date (non/sdy/yy)
			ĺ	l mpiantau, Giva Dai	o jacobijim	I Expin	nau, olve Date (semestyyy)
				8.1s this a Single-use De	evice that was Re	processed	and Reused on a Patient?
			9.If Yes to Item No. 8, Enter Name and Address of Reprocessor				
				9.If Yes to Item No. 8, E	nter Name and A	ddress of R	eprocessor
			i	1			
	lory, Including Preexisting		g., allergies,				
	king and sicoholuse, heps History Reported			10 Daving Available for	Evaluation 2 /2-		0.43
***************************************	man conf. molecutor.	**		10. Device Available for Yes No	Returned to Ma		
							(เกาะได้เล้งของ)
				11. Concomitant Medica	al Products and I	Therapy Dat	es (Exclude treatment of Event)
				E INITIAL DEDC	DTCD		
				E. INITIAL REPO		one#	
				/L\ (C)	- (*)	one w	
				(b) (b)			
				UNITED STATES			
				1			
	f report does not cons		at	2. Health Professional?	3. Occupation	n	4.Initial Reporter Also Sent
	nnel, user facility, imp or product caused or		nt.	Yes X No	File less exess		Report to FDA
				I	1		Yes No X Unk

To: Page 3 of 5 2019-06-13 03:40:41 (GMT) 12679372775 From: Sciformix Corporation

CTU No.: FDA-CDER-CTU-2019-69792 | Department: CFSAN | RCT No.: RCT-408814 | CTU Triage Date: 14-06-2019 | Total Pages

# **MEDWATCH**

3500A Facsimile (Continued)

JNJ	Consumer	US	Cosmetic	

FDA USE ONI	LY
U.S. DEPARTMENT OF HEALTH AN Public Health Service ● Food and	
	FDA Use Onl

Page 2 of 4 F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) H. DEVICE MANUFACTURERS ONLY . Check One 2. UF/Importer Report Number 1. Type of Reportable Event 2. If Follow-up, What Type? User Facility Importer Death Correction 3. User Facility or Importer Name/Address Serious Injury Additional Information Response to FDA Request Malfunction Other: Device Evaluation 4.Device Manufacture Date 3. Device Evaluated by Manufacturer? (mm/vvvv) 4. Contact Person 5. Phone Number Not Returned to Manufacturer Yes Evaluation Summary Attached 6.Date User Facility or Importer 7.Type of Report 8.Date of This Report 5. Labeled for Single Use? No (Attach page to explain why not) or **Became Aware of Event** Initial provide code: (min/dd/yyyy) Yes No Follow-up# 9.Approximate 10. Event Problem Codes (Refer to coding manual) 6. Evaluation Codes (Refer to coding manual) Age of Device Patient Code Method Device 11. Report Sent to FDA? 12. Location Where Event Occurred Results Hospital Outpatient Yes Diagnostic Facility (mm/ddryyyy) Home Conclusions No Nursing Home Ambulatory Surgical 7. If Remedial Action Initiated, 8. Usage of Device 13. Report Sent to Manufacturer? Outpatient Facility Treatment Check Type Initial Use of Device Yes Facility Notification Recall No Reuse Other: Repair Inspection (Specify) Unknown Replace Patient Monitoring 14. Manufacturer Name/Address 9. If action reported to FDA under Relabeling Modification/ 21 USC 360i(f), list correction/ Adjustment removal reporting number: Other: 10 Additional Manufacturer Narrative and/or 11. Corrected Data G. ALL MANUFACTURERS 1. Contact Office - Name/Address (and Manufacturing 2.Phone Number Site for Devices) 60945594 JNJ Consumer US Cosmetic 0.2 199 Grandview Road 3.Report Source Skillman Foreign UNITED STATES Study Literature Consumer 4.Date Received by Manufacturer Health Professional (A)NDA# 06/01/2019 User Facility IND# 6. If IND, Give Protocol # Company Representative STN# Distributor 7. Type of Report (Check all that apply) PMA/ Other: 5-day X 30-day 510(K)# Periodic 7-day Combination ☐ Yes Product 10-day Initial Pre-1938 15-day X Follow-up # OTC Product 9. Manufacturer Report Number 8. Adverse Event Term(s) 1) CHEMICAL POISONING

(Cont.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information, Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to.

US-JNJFOC-20180719747

Department of Health and Human Services Food and Drug Administration - MedWatch 10903 New Hampshire Avenue Building 22, Mall Stop 4447 Silver Spring, MD 20993-0002 OMB Statement:
"An agency may not conduct or sponsor;
and a person is not required to respond
minimation unless
displays a currently valid OMB control
mumber."

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JNJ Consumer US Cosmetic 199 Grandview Road

Skillman

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Mfr. report#: US-JNJFOC-20180719747 Date of this report: 06/12/2019

# B5. Describe Event or Problem (Cont...)

were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.

Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant). Follow up information was received on  $15-\mathrm{JUL}-2018$ .

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Additional information was received on 30-AUG-2018.

This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was

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JNJ Consumer US Cosmetic 199 Grandview Road

Skillman

Continuation Sheet for FDA-3500A Form

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Mfr. report#: US-JNJFOC-20180719747 Date of this report: 06/12/2019

#### B5. Describe Event or Problem (Cont...)

unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information.

This case is a duplicate of 20181013176. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report. Follow up information was received on 13-JAN-2019.

This report contains no new regulatory relevant information. No changes were made to the report. Additional medically important information was received on 13-JAN-2019.

The patient stated that, the product made people sick. Additional medically important information was received from patient on 01-JUN-2019.

On an unspecified date, patient developed formaldehyde poisoning and formaldehyde cancer (chemical poisoning) due to which she was getting sicker and sicker. Patient mentioned that formaldehyde got into her gum skin, eyes, nose, mouth, ears and bones. It was not going away and was affecting her health. The event of chemical poisoning and cancer did not resolve.

Senders Comments/Medical Assessment: ...

# B.6 Relevant Tests/Laboratory Data, Including Dates (Cont...)

Lab Result:

Test NameTest DateTest ResultNormal HighNormal LowBIOPSY??/??/???unknown

## G8. Adverse Event Term (Cont...)

2) PRODUCT FORMULATION ISSUE

U.S. Department of Health and Human Services Food and Drug Administration

MEDWATCH FORM FDA 3500A (10/15)

For use by user-facilities, importers, distributors and manufacturers. for MANDATORY reporting

Page 1 of 4

	See PRA statement or revessor
Mir Report #	US-JNJFOC-20180719747
UF/Importer F	Report#
	FDA Use Only

In Confidence  (b) (6)  Male  (c)  Sto  #1 26-Feb-2017 - #1  Asian	Used
1. Patient Identifier (b) (6)	cal
(b) (6)	
In Confidence  Of Date of Birth for the Feb 192b)  In Confidence  Of Date of Birth for the Feb 192b)  In Confidence  At Therapy Dates (If unknowing give duration) from/ to (or best estimate)) (Idd-minin-yyyy)  #1 26-Feb-2017  #2 5. Diagnosis for Use (Indication)  #2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	cal
In Confidence  Or Date of Birth (e.g., 198 Feb 192b)  In Confidence  Or Date of Birth (e.g., 198 Feb 192b)  In Confidence  S.b. Race (Check all that apply)  Asian	
5.b. Race (Check all that apply)   Asian	ent Abated After Use opped or Dose Reduced?
Asian   American indian or Alaskan Native   Hispanic/Latino   Black or African American   White   Not Hispanic/Latino   Native Hawaiian or Other Pacific Islander   #1 UNKNOWN INDICATION   #2 UNKNOWN INDICATION   #3 UNKNOWN INDICATION   #4 UNKNO	Yes [ No X Doesn'i
Black or African American   White   #1 UNKNOWN INDICATION	
#2 INKNOWN TNETCATION  Re  1. X Adverse Event and/or Product Problem (e.g., defects/maifunctions)  2. Outcome Attributed to Adverse Event (Check sil that apply)  Death Include date (dd-mmm-yyyy):  Life-threatening Disability or Permanent Damage #2 INKNOWN TNETCATION  Re  #1 I Yes No #1 Yes No #2 INC	Yes No X Doesn'i apply
2. Outcome Attributed to Adverse Event (Check ell that apply)  Death Include date (dd-mmm-yyyy):  Life-threatening    Disability or Permanent Damage	ent Reappeared After eintroduction?
Death Include date (did-minim-yyyy):  Life-threatening Disability or Permanent Damage #1 Yes No #1 Yes No #2	Yes No X Doesn'i
☐ Life-threatening ☐ Disability or Permanent Damage #1 ☐ Yes ☐ No #1 ☐ Yes ☐ No	apply
Life woulding Disability of Fathanian Danleys	Yes No X Doesn't
	Оррну
X  Other Serious (Important Medical Events)   8. Expiration Date (cid-mmm-yyyy)   Regulated Intervention to Prevent Permanent Impairment/Damage (Devices)   #1   #2	
C ALL MANUFACTURERS	
S. Date of Event (DO-Infinite-yyyy) 4. Date of this Report (DO-Infinite-yyyy)	Phone Number
Namio 7.	32 754 2672
This spontaneous report received	Report Source
from a patient of unknown age and	(Check all that apply)
gender reporting on self from 1998 Grandview Road Inited States via social media;	Foreign
G00311323.	Study
and the town many religions and	
Manufacture III Committee	Literature
6 Relevant Tests/Laboratory Data, Including Dates	X Consumer
On an unspecified date, the	Health Professional
a biopsy done on her scalp, results   Manufacturer(du-nimm-yyyy)   NDA#	User Facility
unknown. 05 Jan 2020 ANDA# L	Company Representative
ND#	Distributor
CONTINUED	Other
/ Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and atcohol use, liver/kidney problems, etc.)  510(k) #	
7 Type of Report	
(Check all that apply) Combination [77] Yes	
5-day 🗓 36-day	
7-day Poriodic Pre-1938 Yes	
C. SUSPECT PRODUCT(S)	
1. Name, Manufacturer/Compounder, Strength     13-day	
#1 - Name and Strength #1 - NDC # or Unique ID	
OGX EVER CONTINUED S Manufacturer Report Number 5 Adverse Event Term(s) 1 CHEMICAL PO.	TRANTNG
(Chemical p	cisoning
#2 - Name and Strength #2 - NDC # or Unique ID (10008428) ,	Chemical Continued
DGX EVER Continued E. INITIAL REPORTER	
#2 - Manufacturer/Compounder #2 - Lot# 1 Name and Address	Continued
Last Name (b) (6) First Name : (	
2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)   Address : 555   year je st 108	
Concomitant Drugs Not Reported City:(b)(6) State/Province/Regi	ion : (b) (6)
Country: USA ZIP/Postal Coo	The state of the s
11-170	oe (b) (e)
	Initial Reporter Also Sent
personnel, user facility, importer, distributor, manufacturer or product	Report to FDA  Yes No Unk

CTU No.: FDA-CDER-CTU-2020-7931 | Department: CFSAN | RCT No.: RCT-768891 | CTU Triage Date: 22-01-2020 | Total Pages: Continuation Sheet for FDA-3500A Form

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Date of This Report: 21-Jan-2020

#### B. ADVERSE EVENT OR PRODUCT PROBLEM

#### **B.5 Describe Event or Problem (Cont...)**

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified ) for unknown indication. Concomitant medications were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body. Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product

ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant).

Follow up information was received on 15-JUL-2018. This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018. This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018. This report contains no new regulatory relevant information. No changes were made to the

Additional information was received on 30-AUG-2018. Additional information was received on 30-AUG-2018. This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. This case is a duplicate of 20181013176.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the

CTU No.: FDA-CDER-CTU-2020-7931 | Department: CFSAN | RCT No.: RCT-768891 | CTU Triage Date: 22-01-2020 | Total Pages: Continuation Sheet for FDA-3500A Form | Mfr. Report #: 20180719747

Date of This Report: 21-Jan-2020

report.

Follow up information was received on 13-JAN-2019. This report contains no new regulatory relevant information. No changes were made to the

Additional medically important information was received on 13-JAN-2019. The patient stated that, the product made people sick.

Additional medically important information was received from patient on 01-JUN-2019. On an unspecified date, patient developed formaldehyde poisoning and formaldehyde cancer (chemical poisoning) due to which she was getting sicker and sicker. Patient mentioned that formaldehyde got into her gum skin, eyes, nose, mouth, ears and bones. It was not going away and was affecting her health. The event of chemical poisoning and cancer did not resolve.

Additional medically important information was received from patient on 15-AUG-2019. It was determined that Manufacturer Report Number 20190820522 was a duplicate of this case. All relevant information regarding this case will be submitted under Manufacturer Report Number 20180719747.

The following information was updated and incorporated into the case: The patient demographics were updated. It was reported that the patient got sick due to formaldehyde poisoning of her whole body. She lost her hair and her teeth were removed due to the damage the product caused in her mouth and formaldehyde pockets were found in her gums which were not going away. The patient had not recovered from hair loss and formaldehyde pockets in gums and the outcome of product label issue was unknown.

Additional information was received from patient on 15-JUL-2019. The following information was updated and incorporated into the case: The reporter details were updated.

Additional information received from consumer on 27-SEP-2019. Upon review the following information were amended: On an unspecified date, the patient experienced redness on skin, information were amended: On an unspecified date, the patient experienced redness on skin blurriness and watering of the eyes, sores in mouth, infection of ears, nose, throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, snapping and rotting out of product from whole body (application site reaction), damaged skin and bones with swelling pain.

The patient had not recovered from rose throat and skin on whole body, swelling of body, some in mouth, infection of ears, nose throat and skin on whole body, swelling of body. sores in mouth, infection of ears, nose throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, damaged skin and bones with swelling pain and the outcome of snapping and rotting out of product from whole body (application site reaction) was unknown.

The DC/RC was updated from unknown to not applicable for (chemical poisoning, formaldehyde pockets in gums, bumps on body and cracks in head and product snapping and rotting out of whole body). The DC/RC captured as unknown for mouth sores. The event of product quality complaint removed from case.

This case is duplicate of 20190839051, 20190623129, 20180125792, 20180802554, 20181202118 This case is duplicate of 20190939051, 20190623129, 20180125792, 20180902554, 20181202118, 20181217921, 20181113853, 20190609048, 20190821504, 20180133420, 20181117366, 20181216775, 20190822079, 20181013667, 20190626249, 20190701083 and 20180102688.

Version created to amend previously reported information on 27-SEP-2019. Upon review the following information were amended in narrative: The DC/RC captured as unknown for hair loss, bumps on body and cracks in head and product snapping and rotting out of whole body.

Additional information was received from patient on 05-JAN-2020. The following information was updated and incorporated into the case narrative:

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED (topical, dose and frequency unspecified) for unknown indication.

Patient reported that, she had over exposed to formaldehyde and was slowly poisoning herself in and out and all her hair is rotting out of her scalp and body and it made her sick after using the products. It was reported that the patient was experiencing the events from three years and she was still sick and going bald.

Action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED was

unknown.

This case involving the the same patient was linked to case 20200111795.

#### Company Remarks:

## B.6 Relevant Tests/Laboratory Data, Including Dates (Cont...)

#### Lab Result:

Test name Test date Test result Normal value Classification

BIOPSY unknown To: Page 5 of 5 2020-01-21 09:20:14 (GMT) 12679372775 From: Sciformix Corporation

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Date of This Report: 21-Jan-2020

(Biopsy)

## C. SUSPECT PRODUCT(S) (Cont...)

Seq No. C.1 Suspect Product : OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z C.9 Dechallenge :2) N/A UNK : 3) : 4) IINK :5) UNK :6) UNK C.10 Rechallenge N/A:3) UNK :4) UNK :5) UNK :6) UNK Seq No. : 2 C.1 Suspect Product :OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO C.9 Dechallenge :2) N/A : 3) UNK :4) UNK : 5) UNK :6) UNK C.10 Rechallenge :2) N/A :3) UNK :4) UNK

: 5)

:6)

UNK

UNK

## E. INITIAL REPORTER (Cont...)

State: Rhode Island

Email: totalonipper@gmail.com

## G. ALL MANUFACTURERS

#### G.1 Contact Office: Name/Address (and Manufacturing Site for Devices)

United States of America (Printing Unit)

## G.8 Adverse Event Term(s)

1) CHEMICAL POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
2) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))
3) HAIR LOSS (Application site alopecia (10059046), Application site alopecia (10059046))
4) MOUTH SORES (Sores mouth (10049318), Stomatitis (10042128))
5) BUMPS ALL OVER BODY (Application site papules (10049043), Application site papules (10049043))
6) CRACKS IN HEAD AND PRODUCT SNAPPING AND ROTTING OUT OF WHOLE BODY (Application site reaction (10003055), Application site reaction (10003055))

Page 2 of 5 2020-03-02 09:45:48 (GMT) CTU No.: FDA-CDER-CTU-2020-24824 | Department: CFSAN | RCT No.: RCT-786282 | CTU Triage Date: 02-03-2020 | Total Pages
Form Approved: ONB No. 0910-0291, Expires: 9/30/2018 See PRA statement on reverse. U.S. Department of Health and Human Services For use by user-facilities, Mfr Report# US-JNJFOC-20180719747 Food and Drug Administration importers, distributors and manufacturers MEDWATCH for MANDATORY reporting UF/Importer Report # FORM FDA 3500A (10/15) Page 1 of 4 FDA Use Only Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month Route Used 3. Dose Frequency abbreviation, and 4-digit year, for example, 01-Jul-2015. Topical 41 A. PATIENT INFORMATION 1. Patient Identifier | 2. Age 4. Weight X Year(s) Month(s) Topical #2 Week(s) □ Day(s) (b)(6)X Female Therapy Dates (If unknown give duration) from/ to (or best estimate)) (od-mmin-yyyy) [] lb 9. Event Abated After Use or Date of Birth (e.g., 08 Feb 1925) Male Stopped or Dose Reduced? in Confidence (b) (6) Пка #126-Feb-2017 -#1 Yes No X Doesn't 5.a. Ethnicity (Check 5.b. Race (Check all that apply) apply #2 single best enswer) Asian American indian or Alaskan Native 5. Diagnosis for Use (Indication) Hispanic/Latino Yes No X Doesn't Black or African American White apply #1 UNKNOWN INDICATION Not Hispanic/Latino Native Hawaiian or Other Pacific Islander 10. Event Reappeared After B. ADVERSE EVENT OR PRODUCT PROBLEM #2 INKNOWN INDICATION Reintroduction? Product Problem (e.g., defects/malfunctions) X Adverse Event #1 Yes No X Doesn't and/or 2. Outcome Attributed to Adverse Event (Check ell that apply) ි. Is the Product 7. Is the Product Over-Compounded? the-Counter? Death Include date (dd-mmm-yyyy): #2 Yes No X Doesn't ☐ Yes ☐ No Yes No Life-threatening Disability or Permanent Damage Hospitalization - initial or prolonged Congenital Anomaly/Birth Defects Yes No #2 Yes No TOTAL OTHER Serious (Important Medical Events) 6. Expiration Date (dd-mmm-yyyy) #2 #1 Required Intervention to Prevent Permanent Impairment/Damage (Devices) G. ALL MANUFACTURERS 3 Date of Event (dd-mmm-yyyy) 4. Date of this Report (dd-mmm-yyyy) 2. Phone Number 1. Contact Office (and Manufacturing Site for Devices) 28-Feb-2020 732-754-2672 5. Describe Event or Problem JNJ Consumer US Cosmetic 3. Report Source This spontaneous report received from a patient of unknown age and Address (Check all that apply) gender reporting on self from 199 Grandview Road United States via social media: Foreign Skillman, NJ 000311323. Study The patient's weight, height and medical history were unknown. Continued Literature Email Address Continued ngami@its.jnj.com X Consumer 6. Relevant Tests/Laboratory Data, Including Dates Yes Compounding Outsourcing Facility 503B? Health Professional On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results 4. Date Received by User Facility NDA# Manufacturer (dd-mmm-yyyy) Company ANDA# unknown. 19-Feb-2020 Representative IND# Distributor Continued BLA# 6. If IND, Give Protocol # Other Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) PMA 510(k)# 7. Type of Report Combination Yes (Check all that apply) X 30-day 5-day Pre-1938 Yes Periodic OTC Yes C. SUSPECT PRODUCT(S) 10-day Initial 1. Name, Manufacturer/Compounder, Strength 15-day X Follow-up#\_8 #1 - NDC # or Unique ID #1 - Name and Strength 8 Adverse Event Tenn(s)
1) CHEMICAL POISONING
(Chemical poisoning Continued OGX EVER 9. Manufacturer Report Number #1 - Manufacturer/Compounder #1 - 1 000 20180719747 unknown (10008428), Chemical Continued #2 - Name and Strength #2 - NDC # or Unique ID DGK EVER E. INITIAL REPORTER Continued #2 - Manufacturer/Compounder #2 - LON 1 Name and Address Continued Last Name.(b) (6) First Name : (b) (6)

Address : (b) (6)

City: (b) (6)

Country: USA

Professional?

☐ Yes X No

Phone #

2 Health

State/Province/Region; (b) (6)

Email: (b) (6)

3 Occupation

Patlent

ZIP/Postal Code: (b) (6)

4 Imital Reporter Also Sent Report to FDA

Yes No Unk

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

Concomitant Drugs Not Reported

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#### B. ADVERSE EVENT OR PRODUCT PROBLEM

#### B.5 Describe Event or Problem (Cont...)

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified ) for unknown indication. Concomitant medications were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body. Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product

ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant).

Follow up information was received on 15-JUL-2018. This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018. This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018. This report contains no new regulatory relevant information. No changes were made to the

Additional information was received on 30-AUG-2018. Additional information was received on 30-AUG-2018. This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. This case is a duplicate of 20181013176.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information. No changes were made to the CTU No.: FDA-CDER-CTU-2020-24824 | Department: CFSAN | RCT No.: RCT-786282 | CTU Triage Date: 02-03-2020 | Total Pages Continuation Sheet for FDA-3500A Form Mfr. Report #: 20180719747

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report.

unknown.

Follow up information was received on 13-JAN-2019. This report contains no new regulatory relevant information. No changes were made to the report.

Additional medically important information was received on 13-JAN-2019. The patient stated that, the product made people sick.

Additional medically important information was received from patient on 01-JUN-2019. On an unspecified date, patient developed formaldehyde poisoning and formaldehyde cancer (chemical poisoning) due to which she was getting sicker and sicker. Patient mentioned that formaldehyde got into her gum skin, eyes, nose, mouth, ears and bones. It was not going away and was affecting her health. The event of chemical poisoning and cancer did not resolve.

Additional medically important information was received from patient on 15-AUG-2019. It was determined that Manufacturer Report Number 20190820522 was a duplicate of this case. All relevant information regarding this case will be submitted under Manufacturer Report Number 20180719747.

The following information was updated and incorporated into the case: The patient demographics were updated. It was reported that the patient got sick due to formaldehyde poisoning of her whole body. She lost her hair and her teeth were removed due to the damage the product caused in her mouth and formaldehyde pockets were found in her gums which were not going away. The patient had not recovered from hair loss and formaldehyde pockets in gums and the outcome of product label issue was unknown.

Additional information was received from patient on 15-JUL-2019. The following information was updated and incorporated into the case:
The reporter details were updated.

Additional information received from consumer on 27-SEP-2019. Upon review the following information were amended: On an unspecified date, the patient experienced redness on skin, blurriness and watering of the eyes, sores in mouth, infection of ears, nose, throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, snapping and rotting out of product from whole body (application site reaction), damaged skin and bones with swelling pain. The patient had not recovered from redness on skin, blurriness and watering of the eyes, sores in mouth, infection of ears, nose throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, damaged skin and bones with swelling pain and the outcome of snapping and rotting out of product from whole body (application site reaction) was unknown.

The DC/RC was updated from unknown to not applicable for (chemical poisoning, formaldehyde pockets in gums, bumps on body and cracks in head and product snapping and rotting out of whole body). The DC/RC captured as unknown for mouth sores. The event of product quality complaint removed from case.

This case is duplicate of 20190939051, 20190623129, 20180125792, 20180902554, 20181202118, 20181217921, 20181113853, 2019069048, 20190821504, 20180133420, 20181117366, 20181216775, 20190822079, 20181013667, 20190626249, 20190701083 and 20180102688.

Version created to amend previously reported information on 27-SEP-2019. Upon review the following information were amended in narrative: The DC/RC captured as unknown for hair loss, bumps on body and cracks in head and product snapping and rotting out of whole body.

Additional information was received from patient on 05-JAN-2020. The following information was updated and incorporated into the case narrative:
On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED (topical, dose and frequency unspecified) for unknown indication.
Patient reported that, she had over exposed to formaldehyde and was slowly poisoning herself in and out and all her hair is rotting out of her scalp and body and it made her sick after using the products. It was reported that the patient was experiencing the events from three years and she was still sick and going bald.
Action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED was

This case involving the the same patient was linked to case 20200111795.

Additional information was received from patient on 19-FEB-2020. The following information was updated and incorporated into the case narrative:
The patient reported that, she was not using the products from three years and the events were not going away and was spreading. All the bones and soft tissues in her face, neck, head, throat, ears, eyes, nose and mouth are swelling and in pain and all her hair got rotted off from her whole body and it was all rotting out of her scalp permanently from over exposure to toxic formaldehyde poisoning. The patient reported that she had to visit the hospital and to physician every day for the treatment.

On an unspecified, the OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z (OGX BEAUTY EVER STRINGHTNER BRIZILAN KERATIN THERAPY CONDITIONER) and OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED was withdrawn.

This case involving the same patient was linked to case 20200238115.

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Date of This Report: 28-Feb-2020

#### Company Remarks:

## B.6 Relevant Tests/Laboratory Data, Including Dates (Cont...)

#### Lab Result:

Test date Test result Normal value Classification Test name

RIOPSY unknown

(Biopsy)

### C, SUSPECT PRODUCT(S) (Cont,..)

Sea	No.	•	7	

C.1 Suspect Product :OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND

130Z C.9 Dechallenge :2) N/A :3) UNK

:4) UNK :5) UNK :6) UNK

:2) C.10 Rechallenge N/A

UNK :4) UNK :5) UNK :6) UNK

Seq No.

C.1 Suspect Product :OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY

SHAMPOO C.9 Dechallenge :2) N/A

:3) UNK :4) UNK :5) UNK :6) UNK

C.10 Rechallenge N/A :3)

UNK :4) UNK :5) UNK :6) UNK

### E, INITIAL REPORTER (Cont...)

State: Rhode Island

Email: totalonipper@gmail.com

## G. ALL MANUFACTURERS

#### G.1 Contact Office: Name/Address (and Manufacturing Site for Devices)

United States of America (Printing Unit)

#### G.8 Adverse Event Term(s)

1) CHEMICAL POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
2) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))
3) HAIR LOSS (Application site alopecia (10059046), Application site alopecia (10059046))
4) MOUTH SORES (Sores mouth (10049318), Stomatitis (10042128))
5) BUMPS ALL OVER BODY (Application site papules (10049043), Application site papules (10049043))

6) CRACKS IN HEAD AND PRODUCT SNAPPING AND ROTTING OUT OF WHOLE BODY (Application site reaction (10003055), Application site reaction (10003055))

FDA 3500B Form Receipt No: RCT-185863

CTU No.: FDA-CDER-CTU-2018-74354 | Department: CFSAN | RCT No.: RCT-185863 | CTU Triage Date: 12-08-2018 | Total Pages

	EST(GMT-05:00) time zone		
Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 35008
Priority	High		
FDA Received Date	11-Aug-2018	CTU Received Date	11-Aug-2018
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	1	1
User/Group			
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Reporter	(b) (6)	(b) (6)	(b) (6)	(b) (6)			
Section A	- About the Proble	m					
	ind of problem was it? all that apply)	Used a product incorrectly  Noticed a problem with the	e effect (including new or worsening sym which could have or led to a problem quality of the product ng from one product maker to another ma				
Date th	ne problem occurred	11-Aug-2018	11-Aug-2018 Yes				
Seriou	s	Yes					
	y of the following happ call that apply)	Hospitalization - admitted of	ermanent harm (for medical devices only	)			
Other	serious/important medi	and the second of the second o					

# Tell us what happened and how it happened (Include as many details as possible)

I got a Brazilian blowdry treatment on my hair and the salon stylist used a product on me that mainly contained methylene glycol.As soon as the procedure began I had redness in my eyes and my eyes started watering profusely.My head started hurting and my skin developed itchiness.I also felt an extreme irritation in my nostrils and the symptoms have not stopped even though it has been 2 hours post treatment. I also experienced bronchoconstruction and could not swallow food for some time. This was the worst adverse reaction I have ever encountered.

List any relevant tests or laboratory data if you know them (Include dates)								

Section B - About the Products

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CTU No.: FDA-CDER-CTU-2018-74354 | Department: CFSAN | RCT No.: RCT-185863 | CTU Triage Date: 12-08-2018 | Total Pages

	Suspect	Yes					
	Primary?	Yes					
	Product Type	Drug/Biologic					
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Açaí Professional Brazilian	Açaí Professional Brazilian Blowout solution				
	Name of the company that makes (or compounds) the product	METHYLENE GLYCOL					
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	Yes					
	Is the Product Over-the-Counter?	Yes					
	Strength		If Other				
	NDC number						
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes					
	Did the problem return if the person started taking or using the product again?	Doesn't Apply					
	Do you still have the product in case we need to evaluate it?	Yes					
	Returned to Manufacturer Date						
Dru	ug Therapy			1 of 1			
	Expiration date						
	Lot number						
	Dosage Form						
	Quantity	Other	If Other	6 Puff(s)			
	Frequency		If Other				
	How was it taken or used	Topical	If Other				
	Date the person first started taking or using the product	11-Aug-2018					
	Date the person stopped taking or using the product	11-Aug-2018					
	Therapy Duration						
	Therapy Ongoing?						
Wh	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to tr	reat) 1 of 1			
	Cosmetic treatment for the hair						

Section C - About the Medical Device			
	Name of medical device		
	Name of the company that makes the medical device		

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CTU No.: FDA-CDER-CTU-2018-74354 | Department: CFSAN | RCT No.: RCT-185863 | CTU Triage Date: 12-08-2018 | Total Pages

Other identifying information (Th locate them)	e model, catalog, lot, seri	al, or UDI number, and the exp	iration date, if you can	
Model #				
Catalog #		-		
Serial #				
Lot#				
Unique Identifier (UDI) #				
Expiry Date				
Was someone operating the medical device when the problem occurred?	1			
For implanted medical devices C	DNLY (such as pacemake	rs, breast implants, etc.)		
Date the implant was put in		Date the implant was taken out (I relevant)	f	
Section D - About the Person W	ho Had the Problem			
Person's Initials	(b) (6)			
Sex	Female			
Age (specify unit of time for age)	26 Year(s)			
Date of Birth				
Weight	62.1 kg(s)			
Ethnicity (Choose only one)	Not Hispanic/Latino			
Race (Check all that apply)	American Indian or Alaskan Na			
	Asian	ino lolaridor		
	White			
	Black or African American			
List known medical conditions (S	Such as diabotos, high blo	and proseure cancer heart dis	oaso or others)	
None None	puerr as diabetes, flight ble	bod pressure, cancer, fleart dis	case, or others)	
Please list all allergies (such as	to drugs, foods, pollen or	others)		
None				
				L_
List any other important informat	tion about the person (sug	ch as smoking, pregnancy, alco	ohol use, etc.)	

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CTU No.: FDA-CDER-CTU-2018-74354 | Department: CFSAN | RCT No.: RCT-185863 | CTU Triage Date: 12-08-2018 | Total Pages

	None	
l io	t all assument prescription medications and medical desires being used	
LIS	st all current prescription medications and medical devices being used.	
	None	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	None	

ction E - About the Person Fill	ing Out This Form		1 of 1
Primary?	Yes		
Reporter is Patient?			
Title			
Last name	(b) (6)		
Middle Name		-	
First name	(b) (6)		
Number/Street	(b) (6)		
City	(b) (6)		
State/Province	(b) (6)		
Country	USA		
ZIP or Postal code	(b) (6)	-	
Telephone number	(b) (6)		
Email address	(b) (6)		
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Today's date	11-Aug-2018		
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No		

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CTU No.: FDA-CDER-CTU-2018-76155 | Department: CFSAN | RCT No.: RCT-187472 | CTU Triage Date: 17-08-2018 | Total Pages

Basic Details							
Company Unit		CDE	R-CTU	Origi	nating Account	FAERS	
Source Medium			O (Drug)		ce Form Type	E2B XML 3500B	
Priority		Rou	, -,		56 1 61111 1 1 1 1 1 1		
FDA Received Date			Aug-2018	CTU	Received Date	16-Aug-2018	
CTU Triage Date		107	tug 2010		Data Entry Date	10 / lug 2010	
Report Type		Spor	ntaneous		rt Classification	Drug	
Assign To		Use	Ļ	Теро	Tt Olassilloation		
User/Group		0361					
Forward to Depart	mont						
•		i	CDER (CDER-OSE-RS	SS-CT	J@fda.hhs.gov) (E2B)		
Case Priority		Dire	ct ————				
Contact							
Case First Reporter	Name		Last Name		Email Address	Phone	
(b) (6	i)		(b) (6)				
Section A - Abou		1					
What kind of pr (Check all that		$\square$	Vere hurt or had a bad side eff	ect (incl	uding new or worsening symptoms)		
(Oncok all that	арріу)	L	Used a product incorrectly which could have or led to a problem				
		Noticed a problem with the quality of the product					
		Had problems after switching from one product maker to another maker					
Date the proble	em occurred		28-Jul-2014				
Serious		Yes					
Did any of the f	following happen?	Hospitalization - admitted or stayed longer					
(Oneck all that	арріу)	Required help to prevent permanent harm (for medical devices only)					
			Disability or health problem				
		☐ Birth defect					
		Life-threatening					
			Death				
Other perious/i	martant madical	Other serious/important medical incident					
incident	mportant medical	1100	ıble breathing				
Tell us what hap	pened and how	it hap	ppened (Include as m	nany d	letails as possib <b>l</b> e)		
Got a brazilian	keratin treatment o	done to	======================================	of my	hair. During the treatment I cou	Id not breathe properly, I	
					eved my symtoms sensation dur		
			ent i nad triuble breatning dandruff and oilt scalp a		oftwn timws felt a burning sensa d not before.	tion in my lungs, nose,	
			F -				
List any relevant	tests or Jahorate	nrv.de	ata if you know them	(Incl.	ide dates)		
ist any relevant tests or laboratory data if you know them (Include dates)							
N/A							
N/A							
N/A							

Section B - About the Products

1 of 1

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CTU No.: FDA-CDER-CTU-2018-76155 | Department: CFSAN | RCT No.: RCT-187472 | CTU Triage Date: 17-08-2018 | Total Pages

	Suspect	Yes			
	Primary?	Yes			
	Product Type	Drug/Biologic			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Clear reconstructor solution			
	Name of the company that makes (or compounds) the product	Pure brazilian			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?				
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
	Do you still have the product in case we need to evaluate it?	No			
	Returned to Manufacturer Date				
Dr	ug Therapy			1 of 1	
Dr	ug Therapy Expiration date			1 of 1	
Dr	Expiration date  Lot number			1 of 1	
Dr	Expiration date  Lot number  Dosage Form			1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used			1 of 1	
Dru	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product		If Other	1 of 1	
Dri	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product		If Other	1 of 1	
Dri	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration	1 Day	If Other	1 of 1	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing ?		If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product or used or using the product or using the product or using the product or used or using the product or used or using the product or used o		If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing ?		If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product or used or using the product or using the product or using the product or used or using the product or used or using the product or used o		If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product or used or using the product or using the product or using the product or used or using the product or used or using the product or used o		If Other  If Other		
Wi	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product or used or using the product or using the product or using the product or used or using the product or used or using the product or used o	oduct? (such as what cor	If Other  If Other		
Wi	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product prod	oduct? (such as what cor	If Other  If Other		

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makes the medical device

CTU No.: FDA-CDER-CTU-2018-76155 | Department: CFSAN | RCT No.: RCT-187472 | CTU Triage Date: 17-08-2018 | Total Pages

Ot loc	her identifying information (The cate them)	e model, cata <b>l</b> og, lot, seria	al, or UD <b>I</b> number, and the e	expiration date, if you can	
	Model #				
	Catalog #				
	Serial #				
	Lot#				
	Unique Identifier (UDI) #				
	Expiry Date				
	Was someone operating the medical device when the problem occurred?				
Fo	r implanted medical devices C	NLY (such as pacemake	rs, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken out relevant)	t (If	
Se	ction D - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Age (specify unit of time for age)	22 Year(s)			
	Date of Birth				
	Weight				
	Ethnicity (Choose only one)	Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaskan Na Native Hawaiian or Other Paci Asian White Black or African American			
Lis	st known medical conditions (S	uch as diabetes, high blo	od pressure, cancer, heart c	lisease, or others)	
	NA				
PΙε	ease list all allergies (such as t	o drugs, foods, pollen or	others)		
	NA				
Lis	t any other important informat	ion about the person (suc	h as smoking, pregnancy, a	cohol use, etc.)	

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CTU No.: FDA-CDER-CTU-2018-76155 | Department: CFSAN | RCT No.: RCT-187472 | CTU Triage Date: 17-08-2018 | Total Pages

	NA	
Lis	st all current prescription medications and medical devices being used.	
	NA NA	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	NA NA	

tion F. About the Develop F	lines Out This Famo	1 -5 1
tion E - About the Person F		1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		·
First name	(b) (6)	
Number/Street		
City		
State/Province		
Country	USA	
ZIP or Postal code		
Telephone number		
Email address		
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	16-Aug-2018	
Did you report this problem to the company that makes the product (the manufacturer/compounder)		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested)	Yes	

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CTU No.: FDA-CDER-CTU-2018-73893 | Department: CFSAN | RCT No.: RCT-185158 | CTU Triage Date: 09-08-2018 | Total Pages

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	09-Aug-2018	CTU Received Date	09-Aug-2018
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	1	1
User/Group			
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem	To the second se		
	nd of problem was it? all that apply)		effect (including new or worsening symptor hich could have or led to a problem	ms)

(Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)  Used a product incorrectly which could have or led to a problem  Noticed a problem with the quality of the product  Had problems after switching from one product maker to another maker	
Date the problem occurred	04-Aug-2018	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm (for medical devices only) Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident	
Other serious/important medical	fever, cough, burning eyes,	

# Tell us what happened and how it happened (Include as many details as possible)

My daughter (14), had a Brazillion blowout hair treatment done at a salon. Within 72 hours, she began coughing, her eyes were burning, her nose was running, She began to feel dizzy and her head started hurting. Her Dr. couldn't diagnose her with anything but put her on an antibiotic on 8/5. It is now one week after the treatment and she still has 100.5 temp. with a cough. No one around her has gotten sick within 7 days.

List any relevant tests or laboratory data if you know them (Include dates)							

Section B - About the Products

1 of 1

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CTU No.: FDA-CDER-CTU-2018-73893 | Department: CFSAN | RCT No.: RCT-185158 | CTU Triage Date: 09-08-2018 | Total Pages

	Suspect	Yes			
	Primary?	Yes			
	Product Type	Drug/Biologic			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazillion Blowout Hair Trea	tnebt		
	Name of the company that makes (or compounds) the product				
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?				
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	No			
	Do you still have the product in case we need to evaluate it?	No			
	Returned to Manufacturer Date				
Dr	ug Therapy			1 of 1	
Dr	Expiration date			1 of 1	
Dr	Expiration date  Lot number			1 of 1	
Dr	Expiration date  Lot number  Dosage Form			1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used			1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking		If Other	1 of 1	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?		If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product the person stopped taking or using the product therapy Duration therapy Duration therapy Ongoing?	oduct? (such as what cor	If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	oduct? (such as what cor	If Other  If Other		
IVVI	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  The was the person using the product prod		If Other  If Other		
IVVI	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product the person stopped taking or using the product therapy Duration therapy Duration therapy Ongoing?		If Other  If Other		

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makes the medical device

CTU No.: FDA-CDER-CTU-2018-73893 | Department: CFSAN | RCT No.: RCT-185158 | CTU Triage Date: 09-08-2018 | Total Pages

Other identifying information (Th locate them)	e model, cata <b>l</b> og, lot, seri	al, or UDI number, and the $\epsilon$	expiration date, if you can	
Model #				
Catalog #				
Serial #				
Lot #				
Unique Identifier (UDI) #				
Expiry Date		-		
Was someone operating the medical device when the problem occurred?				
For implanted medical devices C	NLY (such as pacemake	rs, breast implants, etc.)		
Date the implant was put in		Date the implant was taken ou relevant)	t (If	
Section D - About the Person Wi	no Had the Problem			
Person's Initials	(b) (6)			
Sex	Female			
Age (specify unit of time for age)				
Date of Birth	(b) (6)	_		
Weight	56.25 kg(s)			
Ethnicity (Choose only one)	Not Hispanic/Latino			
Race (Check all that apply)	American Indian or Alaskan Native Hawaiian or Other Paci Asian White Black or African American			
List known medical conditions (S	Buch as diabetes, high blo	ood pressure, cancer, heart o	disease, or others)	
none				
Please list all allergies (such as t	o drugs, foods, pollen or	others)		
none				
List any other important informat	ion about the person (suc	ch as smoking, pregnancy, a	lcohol use. etc.)	

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CTU No.: FDA-CDER-CTU-2018-73893 | Department: CFSAN | RCT No.: RCT-185158 | CTU Triage Date: 09-08-2018 | Total Pages

	no health problems ircallergies	
Lis	st all current prescription medications and medical devices being used.	
	amoxicillin -tobtreat symptoms	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	none	

ction E - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	09-Aug-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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CTU No.: FDA-CDER-CTU-2018-77677 | Department: CFSAN | RCT No.: RCT-189054 | CTU Triage Date: 23-08-2018 | Total Pages

	ayed in the report are in EST(G	MT <b>-</b> 05:	(00) time zone				
Basic Det		ODE	-D OTH	0	ı: A ı	FAFDO	
Company			ER-CTU		nating Account	FAERS	
Source Medium Priority		MWO (Drug)		Source Form Type		E2B XML 3500B	
		Rou	Routine				
FDA Rece	ived Date	22 <b>-</b> A	Aug-2018	CTU	Received Date	22-Aug-2018	
CTU Triag	e Date			CTU	Data Entry Date		
Report Typ	ре	Spo	ntaneous	Repo	rt Classification	Drug	
Assign To		Use	r				
User/Grou	p						
Forward to	Department	V	CDER (CDER-OSE-RS	SS-CT	J@fda.hhs.gov) (E2B)		
Case Prior	ity	Dire	ct				
Contact							
Case Reporter	First Name		Last Name		Email Address	Phone	
IXeporter 🔽	(b) (6)		(b) (6)		(b) (6)	(b) (6)	
	- About the Problem						
	ind of problem was it?						
Date the Serious Did any (Check	of the following happen? all that apply) at happened and how Brazilian blowout hair stra	No  PH  21-A  No  FF  C  C  it hap  ighten  as so	Jsed a product incorrectly which Jsed a problem with the qualitad problems after switching from Jsec.  Jsec.	al incider	ger im (for medical devices only)  details as possible)  yes and throat were burn went to sleep for maybe	er	
List any re	elevant tests or laborate	ory da	ata if you know them	(Inclu	ide dates)		
Section B	- About the Products	1				1 of 1	
Suspec	t	Yes				_	
Primar	/?	Yes					

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: 4

	Product Type	Drug/Biologic			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian Blowout			
	Name of the company that makes (or compounds) the product	Don't know			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?				
	Strength		If Other		
	NDC number			,	
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
	Do you still have the product in case we need to evaluate it?	No			
	Returned to Manufacturer Date				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Therapy Duration				
	Therapy Ongoing ?				
Wł	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to tr	reat) 1 of 1	
	Hair straightening treatment				
Se	ction C - About the Medical De	evice			

Se	ction C - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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CTU No.: FDA-CDER-CTU-2018-77677 | Department: CFSAN | RCT No.: RCT-189054 | CTU Triage Date: 23-08-2018 | Total Pages

	Model #				
	Catalog #				_
	Serial #				_
	Lot #				_
	Unique Identifier (UDI) #				
	Expiry Date				
	Was someone operating the medical device when the problem occurred?				
Fo	r implanted medical devices C	NLY (such as pacemake	rs, breast imp <b>l</b> ants, etc <b>.</b> )		
Da	ate the implant was put in		Date the implant was taken ou relevant)	ut (If	
Se	ection D - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			_
	Age (specify unit of time for age)				
	Date of Birth	(b) (6)			
	Weight				_
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaskan Na Native Hawaiian or Other Pacif Asian White Black or African American			
Lis	st known medical conditions (S	uch as diabetes. high blo	od pressure. cancer. heart o	disease. or others)	
	N/A				
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o	others)		
Lis	t any other important informat	on about the person (suc	h as smoking, pregnancy, a	alcohol use, etc.)	

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CTU No.: FDA-CDER-CTU-2018-77677 | Department: CFSAN | RCT No.: RCT-189054 | CTU Triage Date: 23-08-2018 | Total Pages

List all current prescription medi	ations and medical devices being used.	
List all over-the-counter medicat	ons and any vitamins, minerals, supplements, and herbal remedies being used.	

ction E - About the Person Fi	ing Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street		
City		
State/Province		
Country	USA	
ZIP or Postal code		
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	22-Aug-2018	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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CTU No.: FDA-CDER-CTU-2018-78373 | Department: CFSAN | RCT No.: RCT-189754 | CTU Triage Date: 24-08-2018 | Total Pages

All dates displayed in the report are in EST(GMT-05:00) time zone

ails					
	CDER-CTU	Origi	nating Account	FAERS	
	MWO (Drug)		-	E2B XML 3500B	
	, -,	Routine			
ved Date		СТИ	Received Date	24-Aug-2018	
	2.7.6.9 20.0			2.7.69 20.0	
	Spontaneous		-	Drug	
<u> </u>					
<u> </u>		RSS-CT	U@fda.hhs.gov) (E2B)		
ty	Direct				
First Name	Last Name		Email Address	Phone	
(b) (6)	(b) (6)				
	(2) (3)				
- About the Prob <b>l</b> em					
all that apply) e problem occurred of the following happen? all that apply)	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  22-Aug-2018  Yes  Hospitalization - admitted or stayed longer  Required help to prevent permanent harm (for medical devices only)  Disability or health problem  Birth defect  Life-threatening  Death				
	Asthma attack				
air cut at (b) (4) ayed onto my hair. The fra stamines and inhaler for r ter 6 shampooings. I do no	. a spray p agrance in this product caus nore than a day. The fragra ot have the container for this	roduct c ed a sei nce was s produc	alled "Regis Enchanted Midnight ious allergic reaction and asthma very persistant and could not be t since it is owned by the salon.	a which required the use	
	- About the Problem and of problem was it? all that apply)  e problem occurred  of the following happen? all that apply)  erious/important medical  at happened and how tair cut at (b) (4) ayed onto my hair. The fra istamines and inhaler for reter 6 shampooings. I do not	Dirit CDER-CTU  dium MWO (Drug)  Routine  ved Date 24-Aug-2018  Be Date  Be Spontaneous  User  Department  CDER (CDER-OSE-Form of the following happen? all that apply)  Problem occurred  Problem occurred  C2-Aug-2018  Yes  Of the following happen? all that apply)  About the Problem occurred  C2-Aug-2018  According to the following happen? all that apply)  All that apply)  According to the following happen? all that apply of the following happen? all that apply occurred  According to the following happen? all that apply occurred	Init CDER-CTU Origi  dium MWO (Drug) Sour  Routine  Ved Date 24-Aug-2018 CTU  e Spontaneous Repo  User  Department CDER (CDER-OSE-RSS-CTI  by Direct  First Name Last Name  (b) (6) (b) (6)  - About the Problem  and of problem was it? all that apply) Were hurt or had a bad side effect (incl  Noticed a problem with the quality of the Had problems after switching from one  to problem occurred 22-Aug-2018  Yes  of the following happen? Hospitalization - admitted or stayed lon Required help to prevent permanent had Disability or health problem  Birth defect Council Disability or health problem  Birth defect Council Disability or health problem  Birth defect Council Disability or health problem  Cother serious/important medical incide Asthma attack  at happened and how it happened (Include as many of the fragrance was iter 6 shampooings. I do not have the container for this product caused a serious for this product caused a serious and inhaler for more than a day. The fragrance was iter 6 shampooings. I do not have the container for this product	Unit CDER-CTU Originating Account dium MWO (Drug) Source Form Type  Routine  Ved Date 24-Aug-2018 CTU Received Date CTU Data Entry Date Report Classification  User  Department CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)  Direct  First Name Last Name Email Address  (b) (6) (b) (6)  - About the Problem all that apply)  Direct Service a problem occurred 22-Aug-2018  Yes  Of the following happen? All that apply)  Disability or health problem Sith defect Line College and Line College	

Section B - About the Products

1 of 1

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CTU No.: FDA-CDER-CTU-2018-78373 | Department: CFSAN | RCT No.: RCT-189754 | CTU Triage Date: 24-08-2018 | Total Pages

	Suspect	Yes			
	Primary?	Yes			
	Product Type	Drug/Biologic			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Enchanted Midnight leave in	n with keratin		
	Name of the company that makes (or compounds) the product	Regis			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?	Yes			
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
	Do you still have the product in case we need to evaluate it?	No			
	Returned to Manufacturer Date				
Dru	ug Therapy			1 of 1	
	Expiration date				
	I - 4 I				
	Lot number				
	Dosage Form		Mov.		
	Dosage Form Quantity		If Other		
	Dosage Form Quantity Frequency		If Other		
	Dosage Form Quantity Frequency How was it taken or used	Topical			
	Dosage Form Quantity Frequency	Topical 22-Aug-2018	If Other		
	Dosage Form Quantity Frequency How was it taken or used Date the person first started		If Other		
	Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking	22-Aug-2018	If Other		
	Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	22-Aug-2018 22-Aug-2018	If Other  If Other		
Wr	Dosage Form Quantity Frequency How was it taken or used Date the person first started taking or using the product Date the person stopped taking or using the product Therapy Duration Therapy Ongoing?  The was the person using the product	22-Aug-2018 22-Aug-2018	If Other  If Other	reat) 1 of 1	
    Wr	Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	22-Aug-2018 22-Aug-2018	If Other  If Other	reat) 1 of 1	
lWr	Dosage Form Quantity Frequency How was it taken or used Date the person first started taking or using the product Date the person stopped taking or using the product Therapy Duration Therapy Ongoing?  The was the person using the product	22-Aug-2018 22-Aug-2018	If Other  If Other	reat) 1 of 1	
  Wr	Dosage Form Quantity Frequency How was it taken or used Date the person first started taking or using the product Date the person stopped taking or using the product Therapy Duration Therapy Ongoing?  The was the person using the product	22-Aug-2018 22-Aug-2018	If Other  If Other	reat) 1 of 1	
lWr	Dosage Form Quantity Frequency How was it taken or used Date the person first started taking or using the product Date the person stopped taking or using the product Therapy Duration Therapy Ongoing?  The was the person using the product	22-Aug-2018 22-Aug-2018	If Other  If Other	reat) 1 of 1	

Se	ection C - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		

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CTU No.: FDA-CDER-CTU-2018-78373 | Department: CFSAN | RCT No.: RCT-189754 | CTU Triage Date: 24-08-2018 | Total Pages

Ot loc	her identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the ex	xpiration date, if you can	
	Model #				
	Catalog #		-		
	Serial #				
	Lot#		_		
	Unique Identifier (UDI) #				
	Expiry Date				
	Was someone operating the medical device when the problem occurred?				
Fo	r implanted medical devices C	NLY (such as pacemake	rs, breast imp <b>l</b> ants, etc.)		
Da	ate the implant was put in		Date the implant was taken out relevant)	(If	
Se	ction D - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Age (specify unit of time for age)	33 Year(s)			
	Date of Birth		-		
	Weight	58.5 kg(s)			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaskan Na	ative		
		Native Hawaiian or Other Paci	fic Islander		
		Asian White			
		Black or African American			
Lis	t known medical conditions (S	uch as diabetes, high blo	od pressure, cancer, heart di	sease, or others)	
	Ashtma, hypothyroidism				
Ple	ease list all allergies (such as t	o drugs, foods, pollen or	others)		i i
	Pollen, cats, some fragrances				
	st any other important informat	ion about the page (ave	h as amaking programme	achol una eta)	
	anv otner important imormat	ion about the person (Suc	n as smoking, pregnancy, al	JOHOL USE. EIC.)	

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CTU No.: FDA-CDER-CTU-2018-78373 | Department: CFSAN | RCT No.: RCT-189754 | CTU Triage Date: 24-08-2018 | Total Pages

Lis	st all current prescription medications and medical devices being used.	
	Synthroid	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	None	

tion E - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	24-Aug-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

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CTU No.: FDA-CDER-CTU-2018-78467 | Department: CFSAN | RCT No.: RCT-190071 | CTU Triage Date: 26-08-2018 | Total Pages

	yed in the report are in EST(G	MT <b>-</b> 05:	(00) time zone					
Basic Deta		ODE	-D OTH	0 : :	1: A 1	FAED		
Company U			R-CTU	Originating Account		FAER		
Source Me	dium		O (Drug)	Sour	ce Form Type	E2B X	(ML 3500B	
Priority		Routine						
FDA Recei	ved Date	26-Aug-2018		CTU	Received Date	26 <b>-</b> Au	ıg <b>-</b> 2018	
CTU Triage Date				CTU	Data Entry Date			
Report Type			ntaneous	Repo	ort Classification	Drug		
Assign To		Use	User					
User/Group								
Forward to	Department	V	CDER (CDER-OSE-RS	SS-CT	U@fda.hhs.gov) (E2B)			
Case Priori	ty	Dire						
Contact								
Case	First Name		Last Name		Email Address	Pho	ne	
Reporter	(b) (6)		(b) (6)		(b) (6)	(b)	(6)	
Ø	(5) (5)		(6) (6)		(b) (0)	(0)	(0)	
Section A	- About the Prob <b>l</b> em							
What kind of problem was it? (Check all that apply)  Were hurt or had a bad side effect (including new or worsening symptoms) Used a problem with the quality of the product Had problems after switching from one product maker to another maker  Date the problem occurred  Serious  No  Did any of the following happen? (Check all that apply)  Hospitalization - admitted or stayed longer Required help to prevent permanent harm (for medical devices only) Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident  Tell us what happened and how it happened (Include as many details as possible)  Reaction to Brazilian blowout. Tight chest, burning nose and throat stinging watery eyes and headache								
It contai	levant tests or laboratons formaldehyde when he About the Products				ude dates)		1 of 1	
Primary		Yes						

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CTU No.: FDA-CDER-CTU-2018-78467 | Department: CFSAN | RCT No.: RCT-190071 | CTU Triage Date: 26-08-2018 | Total Pages

	Product Type	Drug/Biologic			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout			
	Name of the company that makes (or compounds) the product	Brazilian blowout			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?				
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?				
	Did the problem return if the person started taking or using the product again?				
	Do you still have the product in case we need to evaluate it?	Yes			
	Returned to Manufacturer Date				
$oxed{oxed}$					
Dr	ug Therapy			1 of 1	
Dr	Expiration date			1 of 1	
Dr	Expiration date  Lot number			1 of 1	
Dr	Expiration date			1 of 1	
Dr	Expiration date  Lot number		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form		If Other If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity	Other		product is flat ironed into the hair	
Dru	Expiration date  Lot number  Dosage Form  Quantity  Frequency	Other	If Other	product is flat ironed into the	
Dri	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started	Other	If Other	product is flat ironed into the	
Dri	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking	Other	If Other	product is flat ironed into the	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?		If Other  If Other	product is flat ironed into the hair	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product the product or using the product therapy Duration therapy Ongoing?		If Other  If Other	product is flat ironed into the hair	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?		If Other  If Other	product is flat ironed into the hair	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product the product or using the product therapy Duration therapy Ongoing?		If Other  If Other	product is flat ironed into the hair	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product the product or using the product therapy Duration therapy Ongoing?		If Other  If Other	product is flat ironed into the hair	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product the product or using the product therapy Duration therapy Ongoing?		If Other  If Other	product is flat ironed into the hair	

S	ection C - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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CTU No.: FDA-CDER-CTU-2018-78467 | Department: CFSAN | RCT No.: RCT-190071 | CTU Triage Date: 26-08-2018 | Total Pages

	Model #				
	Catalog #				
	Serial #		_		
	Lot #				
	Unique Identifier (UDI) #				
	Expiry Date				
	Was someone operating the medical device when the problem occurred?				
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast imp <b>l</b> ants, etc <b>.</b> )		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ction D - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Age (specify unit of time for age)	36 Year(s)			
	Date of Birth				
	Weight	65.25 kg(s)			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaskan Na	ative		
		Native Hawaiian or Other Pacif	fic Islander		
		Asian			
		White			
		Black or African American			
Lis	st known medical conditions (S	uch as diabetes, high blo	od pressure, cancer, heart disea	ise, or others)	
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o	others)		
Lis	t any other important informati	on about the person (suc	h as smoking, pregnancy, alcoh	ol use, etc.)	

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CTU No.: FDA-CDER-CTU-2018-78467 | Department: CFSAN | RCT No.: RCT-190071 | CTU Triage Date: 26-08-2018 | Total Pages

List all current prescription medications and medical devices being used.	
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedie	s being used.

tion E - About the Person	Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(b) (6)	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	26-Aug-2018	
Did you report this problem to company that makes the prod (the manufacturer/compounde	ıct	
If you do NOT want your identity disclosed to the manufacturer, please mark thi box (Confidentiality Requested		

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CTU No.: FDA-CDER-CTU-2018-90397 | Department: CFSAN | RCT No.: RCT-203012 | CTU Triage Date: 01-10-2018 | Total Pages

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Detai <b>l</b> s			_
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	01-Oct-2018	CTU Received Date	01-Oct-2018
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-OSE-R	SS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct	<u>50 0 1 0 @.ua.iiii 0 go 17 (2227</u>	
Contact			
Case First Name	Last Name	Email Address	Phone
Reporter (b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A - About the Problem			
What kind of problem was it?			
(Check all that apply)	8 S	ffect (including new or worsening symptoms	,)
	Noticed a problem with the qua	ich could have or led to a problem	
	1 T T	from one product maker to another maker	
Date the problem occurred	29-Sep-2018	Toni one product maker to another maker	
Serious	Yes		
Did any of the following happen?	<u> </u>		
(Check all that apply)	Hospitalization - admitted or st	•	
	Disability or health problem	nanent harm (for medical devices only)	
	Birth defect		
	Life-threatening		
	Death		
	Other serious/important medic	al incident	
Tell us what happened and how			
person who did the treatment on idizzy, now it is 3 days later and I am having severe nuerological iss	me kept applying it directly to feel unbalanced, dizzy, slurre sues	out treatment. I had this done on S my scalp, which is not supposed t d speech., these chemicals have a	o be down. 2 hours later I felt
List any relevant tests or laborate	bry data if you know them	(Include dates)	
Section B - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		

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CTU No.: FDA-CDER-CTU-2018-90397 | Department: CFSAN | RCT No.: RCT-203012 | CTU Triage Date: 01-10-2018 | Total Pages

	Product Type	Drug/Biologic		-	
	Name of the product as it	Brazilian Blowout			
	appears on the box, bottle, or package (Include as many names as you see)	Brazilian Blowout			
	Name of the company that makes (or compounds) the product	Brazilian Blowout	_		
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?		-		
	Strength		If Other		
	NDC number			,	
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?				
	Do you still have the product in case we need to evaluate it?	No			
	Returned to Manufacturer Date				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form		,		
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product	29-Sep-2018			
	Date the person stopped taking or using the product				
	Therapy Duration			-	
	Therapy Ongoing ?				
Wh	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to tr	reat) 1 of 1	
	to smooth hair				
	ction C - About the Medical De				
_					

S	ection C - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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CTU No.: FDA-CDER-CTU-2018-90397 | Department: CFSAN | RCT No.: RCT-203012 | CTU Triage Date: 01-10-2018 | Total Pages

	Model #				
	Catalog #				
	Serial #				
	Lot #				
	Unique Identifier (UDI) #	-			
	Expiry Date  Was someone operating the medical device when the problem occurred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ction D - About the Person Wh	o Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Age (specify unit of time for age)	39 Year(s)			
	Date of Birth	(-)	-		
	Weight	60.75 kg(s)			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)				
		American Indian or Alaskan Na			
		Asian	Cisianuei		
		White			
		Black or African American			
LIS		uch as diabetes, nigh bloc	od pressure, cancer, heart dise	ease, or otners)	
	none				
Ple	ease list all allergies (such as t	o drugs, foods, pollen or c	others)		
	none				
Lis	t any other important informati	on about the person (suc	n as smoking, pregnancy, alco	hol use, etc.)	

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CTU No.: FDA-CDER-CTU-2018-90397 | Department: CFSAN | RCT No.: RCT-203012 | CTU Triage Date: 01-10-2018 | Total Pages

List all current prescription medications and medical devices being used.	
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedie	s being used.

ction E - About the Person Fill	ling Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	-
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	01-Oct-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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CTU No.: FDA-CDER-CTU-2018-94047 | Department: CFSAN | RCT No.: RCT-207238 | CTU Triage Date: 11-10-2018 | Total Pages

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic De	otails	W11-05.00) time zone				
Compan		CDER-CTU	Origin	nating Account	FAERS	
Source N		MWO (Drug)		ce Form Type	E2B XML 3500E	
	wedium	Routine	Source	се гопп туре	EZB XIVIL 3300E	
Priority	ceived Date	11-Oct-2018	CTU	Received Date	11-Oct-2018	
		11-00l-2016			11-00-2016	
	age Date 	Consistence		Data Entry Date	Davis	
Report T		Spontaneous	Repo	rt Classification	Drug	
Assign T		User				
User/Gro						
	to Department	☑ CDER (CDER-OSE	-RSS-CTI	J@fda.hhs.gov) (E2B)		
Case Pri	iority	Direct				
Contact						
Case Reporter	First Name	Last Name		Email Address	Phone	
✓	(b) (6)	(b) (6)				
	A - About the Problem tkind of problem was it?					
Date Serio Did a (Che	the problem occurred bus iny of the following happen? ck all that apply)  what happened and how d the Cezanne Smoothing Tr natural ingredients. After apple and my chest felt tight and have to a product containing	No  Hospitalization - admitted of Required help to prevent policy in the alth problem Birth defect Life-threatening Death Other serious/important medit happened (Include as reatment on a client. It proplying the product to the client heavy. I needed to lea	which could quality of the ng from one or stayed longermanent has a many comises to help the could be not shair,	have or led to a problem e product product maker to another make  ger rm (for medical devices only)  at letails as possible) ave no odor, no smell, no there was a very strong	o formaldehyde, and be r	ediate
List anv	relevant tests or laborate	orv data if you know the	em (Inclu	de dates)		
I rese	earched the chemicals in the dehyde.	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	<u> </u>	that galoxyloyl carbocys	teine is
Section	B - About the Products				1	of 1
Susp	ect	Yes				
Prima	ary?	Yes				

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CTU No.: FDA-CDER-CTU-2018-94047 | Department: CFSAN | RCT No.: RCT-207238 | CTU Triage Date: 11-10-2018 | Total Pages

locate them)

	Product Type	Drug/Biologic	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Cezanne Classic Keratin Smoothing Treatment	
	Name of the company that makes (or compounds) the product	Cezanne	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		
	Is the Product Over-the-Counter?		
	Strength	If Other	
	NDC number		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?		
	Did the problem return if the person started taking or using the product again?		
	Do you still have the product in case we need to evaluate it?	No	
	Returned to Manufacturer Date		
Dr	ug Therapy		1 of 1
	Expiration date	01-Jan-2019	
	Lot number	01-Jan-2019	
	•	01-Jan-2019	
	Lot number	01-Jan-2019  If Other	
	Lot number  Dosage Form		
	Lot number  Dosage Form  Quantity	If Other	
	Lot number  Dosage Form  Quantity  Frequency	If Other If Other	
	Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started	If Other If Other	
	Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product	If Other If Other	
Wir	Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	If Other If Other	1 of 1
ĮWH	Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	If Other If Other If Other	1 of 1
WI	Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	If Other If Other If Other	1 of 1
	Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product person using the person using the product person using the produ	If Other If Other If Other oduct? (such as what condition was it supposed to treat)	1 of 1
	Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  The was the person using the product person using the person using the product person using the produ	If Other If Other If Other oduct? (such as what condition was it supposed to treat)	1 of 1
	Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product person using the person using the product person using the produ	If Other If Other If Other oduct? (such as what condition was it supposed to treat)	1 of 1

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Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can

CTU No.: FDA-CDER-CTU-2018-94047 | Department: CFSAN | RCT No.: RCT-207238 | CTU Triage Date: 11-10-2018 | Total Pages

	Model #							
	Catalog #							
	Serial #							
	Lot #							
	Unique Identifier (UDI) #							
	Expiry Date							
	Was someone operating the medical device when the problem occurred?							
Fo	r implanted medical devices C	NLY (such as pacemake	rs, breast implants, etc.)					
Date the implant was put in			Date the implant was taken out (If relevant)					
Se	ction D - About the Person Wh	no Had the Problem						
	Person's Initials	(b) (6)						
	Sex	Female						
	Age (specify unit of time for age)	36 Year(s)						
	Date of Birth							
	Weight	58.5 kg(s)						
	Ethnicity (Choose only one)	Not Hispanic/Latino						
	Race (Check all that apply)	American Indian or Alaskan Na	ative					
		Native Hawaiian or Other Pacific Islander						
		Asian						
		White						
		Black or African American						
Lis	st known medical conditions (S	uch as diabetes, high blo	od pressure, cancer, heart dise	ase, or others)				
	none							
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o	others)					
	penicillin							
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)								
	none							

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CTU No.: FDA-CDER-CTU-2018-94047 | Department: CFSAN | RCT No.: RCT-207238 | CTU Triage Date: 11-10-2018 | Total Pages

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

ction E - About the Person F	lling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street		
City		
State/Province		
Country	USA	
ZIP or Postal code		
Telephone number		
Email address		
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	11-Oct-2018	
Did you report this problem to the company that makes the produce (the manufacturer/compounder)	ıt	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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CTU No.: FDA-CDER-CTU-2018-94908 | Department: CFSAN | RCT No.: RCT-208263 | CTU Triage Date: 15-10-2018 | Total Pages

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details										
Company Unit	CDER-CTU	Originating Account	FAERS							
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B							
Priority	Routine	Routine								
FDA Received Date	15-Oct-2018	CTU Received Date	15-Oct-2018							
CTU Triage Date		CTU Data Entry Date								
Report Type	Spontaneous	Report Classification	Drug							
Assign To	User									
User/Group										
Forward to Department	CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)									
Case Priority	Direct									
	I.									
Contact										
Case First Name Reporter	Last Name	Email Address	Phone							
(b) (6)	(b) (6)	(b) (6)	(b) (6)							
Section A - About the Problem		·	·							
What kind of problem was it?	[7]		,							
(Check all that apply)	R - 23	Were hurt or had a bad side effect (including new or worsening symptoms)								
	Used a product incorrectly which could have or led to a problem  Noticed a problem with the quality of the product									
	Had problems after switching from one product maker to another maker									
Date the problem occurred  13-Oct-2018										
Serious	Yes									
Did any of the following happen?	Hospitalization - admitted or stayed longer									
(Check all that apply)	Required help to prevent permanent harm (for medical devices only)									
	Disability or health problem									
	Birth defect									
	Life-threatening									
	Death									
	Other serious/importar	nt medical incident								
Tell us what happened and how	it happened (Inc <b>l</b> ude	e as many details as possib <b>l</b> e)								
		coworkers was performing a Brazilian B								
pains and trouble breathing my	pains and trouble breathing my symptoms are gradually getting better, now it's more of a stinging, raw feeling in my lungs.									
List any relevant tests or laboratory data if you know them (Include dates)										
	_									
Section B - About the Products			1 of 1							
Suspect	Yes									
Primary?	Yes									

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Receipt No: RCT-208263 CTU No.: FDA-CDER-CTU-2018-94908   : 4	Department: CFSAN   RCT No.:	RCT-208263   CTU Triage Date: 15	FDA 3500B Form -10-2018   Total Pages
Product Type	Drug/Biologic		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazillian Blowout smoothin	ng system	
Name of the company that makes (or compounds) the product	Brazilian Blowout		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?			
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?			
Do you still have the product in case we need to evaluate it?	Yes		
Returned to Manufacturer Date			
Drug Therapy			1 of 1
Expiration date			

Drug Therapy			1 01 1
Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started taking or using the product	13-Oct-2018	,	,
Date the person stopped taking or using the product			
Therapy Duration			
Therapy Ongoing ?			

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

1 of 1

Smoothing hair

Se	ection C - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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Receipt No: RCT-208263 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2018-94908 | Department: CFSAN | RCT No.: RCT-208263 | CTU Triage Date: 15-10-2018 | Total Pages

	Model #			
	Catalog #			
	Serial #			
	Lot#			
	Unique Identifier (UDI) #			
	Expiry Date			
	Was someone operating the medical device when the problem occurred?			
Fo	r imp <b>l</b> anted medical devices O	NLY (such as pacemakers	s, breast imp <b>l</b> ants, etc <b>.</b> )	
Da	ate the implant was put in		Date the implant was taken out ( relevant)	If
Se	ction D - About the Person Wh	no Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Female		
	Age (specify unit of time for age)			
	Date of Birth	(b) (6)		
	Weight			
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaskan Nati	ve	
		Native Hawaiian or Other Pacific	sIslander	
		Asian		
		White		
		Black or African American		
Lis	t known medical conditions (S	uch as diabetes, high bloo	d pressure, cancer, heart di	sease, or others)
	Hypothyroidism hashimotos			
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o	thers)	
	Pollen			
Lis	t any other important informati	on about the person (such	as smoking, pregnancy, alc	ohol use, etc.)

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Receipt No: RCT-208263 FDA 3500B Form

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Lis	t all current prescription medications and medical devices being used.	
	Unithroid	
LIS	t all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used,	
LIS	at all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.  Multi vitamin magnesium	
Lis	t all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.  Multi vitamin magnesium	
Lis		
LIS		

ction E - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	15-Oct-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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CTU No.: FDA-CDER-CTU-2018-102199 | Department | CFSAN | RCT No.: RCT-216847 | CTU Triage Date | 06-11-2018 | Total Page

	ils			45.00.00	
ompany L	Init	CDER-CTU	Originating Account	FAERS	
ource Med	muib	MWO (Drug)	Source Form Type	E2B XML 3500B	
riority		High			
FDA Received Date		05-Nov-2018	CTU Received Date	06-Nov-2018	
CTU Triage Date			CTU Data Entry Date		
Report Type		Spontaneous	Report Classification	Drug	
Assign To		User		1	
lser/Group					
orward to	Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)		
ase Priorit	ty	Direct	<u></u>		
ontact			Water Street		
ase Reporter	First Name	Last Name	Email Address	Phone	
2	(b) (6)		100		
	problem occurred	04-Nov-2018			
Date the	problem occurred				
Serious		Yes			
Did any	of the following happen?	119-199			
	all that apply)	Disability or health products  Birth detect  Life-threatening  Death	ent permanent harm (for medical devices only) blem		
(Check a	all that apply)	Required help to preve	ent permanent harm (for medical devices only) blem		
Other se incident	erious/important medical	Required help to preve	ent permanent harm (for medical devices only) blem		

Section B - About the Products

1 of 1

CTU No.: FDA-CDER-CTU-2018-102199 | Department: CFSAN | RCT No.: RCT-216847 | CTU Triage Date: 06-11-2018 | Total Page

	Suspect	Yes			
	Primary?	Yes	Yes		
	Product Type	Drug/Biologic			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	de keratia smoothing sham	poo and de keratina smoothing	conditioner	
	Name of the company that makes (or compounds) the product	Arganatural			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	Yes			
	Is the Product Over-the-Counter?	Yes			
	Strength		If Other		
	NDC number		·		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
	Do you still have the product in case we need to evaluate it?	Yes			
	Returned to Manufacturer Date			_	
Dr	ug Therapy			1 of 1	
	Expiration date		_	_	
	Lot number				
	Dosage Form		,		
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Topical	If Other		
	Date the person first started taking or using the product	04-Nov-2018			
	Date the person stopped taking or using the product	05-Nov-2018			
	Therapy Duration				
	Therapy Ongoing?				
Wł	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to t	treat) 1 of 1	
	Shampoo and conditioner treatme	ent			

3	Section C - About the Medical De	evice
	Name of medical device	
	Name of the company that makes the medical device	

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CTU No.: FDA-CDER-CTU-2018-102199 | Department: CFSAN | RCT No.: RCT-216847 | CTU Triage Date: 06-11-2018 | Total Page

Other identifying information (Th locate them)	e model, cata <b>l</b> og, lot, seria	al, or UDI number, and the ex	xpiration date, if you can	
Model #				
Catalog #				
Serial #				
Lot #				
Unique Identifier (UDI) #				
Expiry Date				
Was someone operating the medical device when the problem occurred?				
For implanted medical devices C	NLY (such as pacemake	rs, breast implants, etc.)		
Date the implant was put in		Date the implant was taken out relevant)	(If	
Section D - About the Person Wi	no Had the Problem			
Person's Initials	(b) (6)			
Sex	Female			
Age (specify unit of time for age)	55 Year(s)			
Date of Birth				
Weight				
Ethnicity (Choose only one)	Not Hispanic/Latino			
Race (Check all that apply)	American Indian or Alaskan Na Native Hawaiian or Other Pacif Asian White Black or African American			
List known medical conditions (S	such as diabetes, high blo	od pressure, cancer, heart d	isease, or others)	
Diabetes				
Please list all allergies (such as t	o drugs, foods, pollen or	others)		
None None	e arage, reede, penerrer	-		
List any other important informat	ion about the person (suc	ch as smoking, pregnancy, al	cohol use, etc.)	

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CTU No.: FDA-CDER-CTU-2018-102199 | Department: CFSAN | RCT No.: RCT-216847 | CTU Triage Date: 06-11-2018 | Total Page s: 4

	N/A	
Lis	at all current prescription medications and medical devices being used.	
	N/A	
LIS	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	N/A	

ction E - About the Person Fill	ing Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		-
Last name	(b) (6)	-
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(b) (6)	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number		
Email address	(b) (6)	-
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	05-Nov-2018	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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CTU No.: FDA-CDER-CTU-2018-103645 | Department: CFSAN | RCT No.: RCT-218975 | CTU Triage Date: 11-11-2018 | Total Page

Company Ur	red in the report are in EST(GI	Jacob mills ratio			
willbally Of	nit	CDER-CTU	Originating Account	FAERS	
ource Medi	ium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority  FDA Received Date  CTU Triage Date  Report Type  Assign To		Routine			
		11-Nov-2018	CTU Received Date	11-Nov-2018	
			CTU Data Entry Date		
		Spontaneous	Report Classification	Drug	
		User			
Jser/Group					
orward to D	Department	CDER (CDER-OS	SE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	y	Direct	3 // / / / / / / / / / / / / / / / / /		
Case Reporter	(b) (6)	(b) (6)	Email Address (b) (6)	Phone	
Serious Did any o	problem occurred of the following happen?	Noticed a problem with the quality of the product  Had problems after switching from one product maker to another maker  05-Nov-2018  Yes  Hospitalization - admitted or stayed longer			
(Check a	ill that apply)		nt permanent harm (for medical devices only)		
		Other serious/important	medical incident		

Section B - About the I	roducts	1 of 1
Suspect	Yes	

CTU No.: FDA-CDER-CTU-2018-103645 | Department: CFSAN | RCT No.: RCT-218975 | CTU Triage Date: 11-11-2018 | Total Page

Name of the company that makes the medical device

	Primary?	Yes			
	Product Type	Drug/Biologic			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian Blowout			
	Name of the company that makes (or compounds) the product	Brazilian Blowout			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?	Yes			
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Yes			
	Do you still have the product in case we need to evaluate it?	Yes			
	Returned to Manufacturer Date				
Dr	ug Therapy			1 of 1	
Dr	ug Therapy Expiration date			1 of 1	
Dr				1 of 1	
Dr	Expiration date			1 of 1	
Dr	Expiration date  Lot number		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity			1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking		If Other	1 of 1	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?		If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product product or using the product or using the product product or using the product or using the product product or using the product or using the product product or using the product or using the product product or using the product or using the product product or using the pr	oduct? (such as what co	If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	oduct? (such as what co	If Other  If Other		
VV	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product  Work		If Other  If Other		
VV	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product product or using the product or using the product product or using the product or using the product product or using the product or using the product product or using the product or using the product product or using the product or using the product product or using the pr		If Other  If Other		

locate them)

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Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can

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	Model #				
	Catalog #				_
	Serial #				
	Lot #				_
	Unique Identifier (UDI) #				
	Expiry Date				_
	Was someone operating the medical device when the problem occurred?				
Fo	r implanted medical devices C	NLY (such as pacemaker	rs, breast imp <b>l</b> ants, etc <b>.</b> )		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ection D - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			_
	Age (specify unit of time for age)				
	Date of Birth	21-May-1987			
	Weight	60 kg(s)			
	Ethnicity (Choose only one)	Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaskan Na Native Hawaiian or Other Pacif Asian White			
		Black or African American			
Lis	st known medical conditions (S	uch as diabetes, high blo	od pressure, cancer, heart dise	ease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o	others)		
Lis	st any other important informat	ion about the person (suc	h as smoking, pregnancy, alco	hol use, etc.)	

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CTU No.: FDA-CDER-CTU-2018-103645 | Department: CFSAN | RCT No.: RCT-218975 | CTU Triage Date: 11-11-2018 | Total Page

Lis	st all current prescription medications and medical devices being used.	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	

tion E - About the Person F	Illing Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street		
City		
State/Province	-	
Country	USA	
ZIP or Postal code		
Telephone number		
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	11-Nov-2018	
Did you report this problem to the company that makes the produce (the manufacturer/compounder)	t	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested)	Yes	

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## Begin a Voluntary Report / Initial Report

Introduction

Report Title

CFSAN CAERS PHONE REPORT 10/21/2019

Did the food or product make someone sick, cause a negative reaction, or some other health problem?

Yes

Was there a problem with the product (e.g., defect in the product such as an unusual odor, taste, or appearance)?

Yes

Reporter Information

Do you wish to remain anonymous to the FDA?

No

First Name Last Name

(b) (6)

**Primary Phone** 

(b) (6)

Mail/Zip Code Country

00000 United States

What is your relationship to the individual affected? The affected individual is your:

I am the affected person

Suspect Product

Product Type Product Name

Cosmetic OGX BRAZILIAN THERAPY STRAIGHTENING CONDITIONER

Affected Individual

Gender Age at the time of event

Female 0 year(s) old

Adverse Event

Outcomes attributed to this adverse event

Other serious/important medical incident

Description of adverse event.

This product is banned in canada. OGX BRAZILIAN THERAPY STRAIGHTENING CONDITIONER. I have formaldehyde poisoning. Others can get sick from this. There are no warnings on the bottles. The FDA sent out a complaint to salons about improper directions in 2011 and is over the limit. Nothing is being done about this and it needs to be removed from the market. I am still sick. This does not belong in the

public. It belongs in the salon where it can be properly used. This is supposed to be taken off the shelf this month and I am not sure why it is not and is still being sold in stores. I have beautiful hair. All my hair has fallen off. I sent pictures of my hair coming out. The EWG is trying to get it off the shelves and FDA is ignoring them. Environmental Womens Group. This effected my gums and tongue and the dentist know its not my teeth. They are telling me it is something else. Formaldehyde is not treatable because they cannot find it. That is how they get away with it. The damages you get from it can't be found. So nothing can be treated. You can get formaldehyde cancer from this. I can't believe what I was reading about this stuff I was putting on my body. The company lied and said it is formaldehyde free and it wasn't and had improper directions on the label. It is supposed to be used once a year by a professional and I was using it once a day like a conditioner. This has been going on for years. I am not sure why it is still going on and is still on the market. The hair came right off my body. ALL of my hair came off and has been going on for almost three years now. I bought this product in 2013 and was using it on and off. I got the issues and got sick, and didn't realize it was this product until I read about this online. It melted my hair like plastic. The symptoms started getting worse and worse. Couldn't believe it was a hair product that did this. Very bad fatigue. My hair is rotting out of my scalp. Turns white then a brown color and falls out of my body. This is a toxic chemical. The FDA has gotten these complaints years ago in 2006, 2011 warnings out to salons. I bought mine in 2013 and would never have bought it if it had been of the shelves. I had long beautiful hair and it is now gone. I sent pictures. The bones in my nose, cheeks have bumps all inside - sores due to this product exposure. Everything I read actually happened to me. This is banned in canada, you can't even buy it in canada. There is a Chinese product similar that you can't buy, but this brazilian product can be still bought on the market. When I started getting symptoms like that, the doctors couldn't find anything. And I realized it was this product. I looked up the FDA reviews/reports on this and I realized it was this product making me sick. I used a whole bottle, and was going to use another one - the second bottle, my hair had turned to plastic and this is what is making me sick. You don't realize that a hair product could do this. The horrible symptoms are coming from this product. I have medical records that can be provided for this issue. Fatigue and facial, neck swelling. Slowly poisoning yourself. I stopped product use but the symptoms are still ongoing. It will have been 3 years no since product discontinue and I am still having symptoms. Swelling and lumps in my nose and head and my hair is destroyed. This product belongs off the market immediately. They are selling salon professional products to the public. There are no directions on the label regarding product use for the public. No notification or warnings of formaldehyde ingredients in the product. I called Johnson and Johnson and reported it. They sent me papers to fill out, but I have not completed them. I am afraid to use anything since I got sick from this. Once you have poisoned by a product, it changes your whole life. Headaches, swollen head, people think i am crazy but when I showed my doctor the stuff I was using - he believed everything I said. I had all kinds of tests due to this product use. The formaldehyde was getting into my soft tissue. The Environmental Women's Group is trying to get this product off the shelf.

Signs, Symptoms, or Diagnoses

**Product Problem Description** 

Attachment

**Document Type** 

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CTU No.: FDA-CDER-CTU-2018-114486 | Department: CFSAN | RCT No.: RCT-231564 | CTU Triage Date: 14-12-2018 | Total Page

	isic Deta	ved in the report are in EST(G	wri-us:uu) time zone				
	ompany U		CDER-CTU	Origi	nating Account	FAERS	
-	ource Med		MWO (Drug)		ce Form Type	E2B XML 3500B	
		num -	Routine	3001	сетопптуре	LZB XIVIL 3300B	
Priority  FDA Received Date		and Data		СТЦ	Descined Date	44 D 2040	
-			14-Dec-2018		Received Date	14-Dec-2018	
	CTU Triage Date		0 1		Data Entry Date	<b>D</b>	
	eport Type	)	Spontaneous	Repo	ort Classification	Drug	
	ssign To		User				
	ser/Group		nent 🗔				
		Department	☑ CDER (CDER-OS	E-RSS-CT	U@fda.hhs.gov) (E2B)		
C	ase Priorit	у	Direct				
Co	ontact						
_	ase eporter	First Name	Last Name		Email Address	Phone	
$\nabla$	3	(b) (6)	(b) (6)			(b) (6)	
١٥٥	action A -	About the Problem					
00		d of problem was it?					
		all that apply)	2 2		uding new or worsening symptoms)		
					have or led to a problem		
			Noticed a problem with the				
	Date the	problem occurred	Had problems after switch	thing f <u>rom one</u>	product maker to another maker		
	Serious	<b>P</b> (000000000000000000000000000000000000	No				
		of the following happen?					
		all that apply)	Hospitalization - admitted	•			
				•	arm (for medical devices only)		
			Disability or health problem				
			☐ Birth defect				
			Life-threatening				
			Death Other serious/important medical incident				
Te	ll us wha	it happened and how	'				
	CFSAN Brazilian this. i ha direction	CAERS PHONE REPOR Everstraight Keratine Th ve no idea how to fix this. s on this bottle. There wa	T: My name is (b) (6) erapy conditioner. I have I am toxically poisoned s a warning out in 2011	I an e called you by formaldo about how	n calling to report a Formaldehyd before. Thigns are getting wors chyde. I have been using it for th dangerous this product was from	e. I am very sick from ree years following n Orpholon. These	
					everyday conditioner, it is a treati e a week. I had a biopsy. i feel v		
					e a week. I had a blopsy. Heel v usely dry, no oils, effected my ey		
L	breathin	g. i am going to end up in	a hospital. i need to kno	w what to	lo.		
Lis	st any rel	evant tests or <b>l</b> aborato	ory data if you know t	hem ( <b>I</b> nclu	ude dates)		

Section B - About the Products

1 of 1

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CTU No.: FDA-CDER-CTU-2018-114486 | Department: CFSAN | RCT No.: RCT-231564 | CTU Triage Date: 14-12-2018 | Total Page

	Suspect	Yes			
	Primary?	Yes			
	Product Type	Drug/Biologic			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian Everstraight Kerati	ne Therapy conditioner		
	Name of the company that makes (or compounds) the product				
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?				
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?				
	Do you still have the product in case we need to evaluate it?				
	Returned to Manufacturer Date				
$\overline{}$	T-1			4 5 4	
Dr	ug Therapy			1 of 1	
Dr	Expiration date			1 of 1	
Dr	Expiration date  Lot number			1 of 1	
Dr	Expiration date  Lot number  Dosage Form			1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used			1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product		If Other	1 of 1	
Dr	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration		If Other	1 of 1	
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?		If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration	oduct? (such as what cor	If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	oduct? (such as what cor	If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	oduct? (such as what cor	If Other  If Other		
	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?	roduct? (such as what cor	If Other  If Other		
IVVI	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product product.		If Other  If Other		
IVVI	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?		If Other  If Other		
IVVI	Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Therapy Duration  Therapy Ongoing?  Thy was the person using the product product or using the product product.		If Other  If Other		

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makes the medical device

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Other ide	entifying information (The em)	e model, catalog, lot, seria	al, or UDI number, and the	expiration date, if you can	
Mode	I #				
Catalo	og #				
Serial	#				
Lot #				-	
Uniqu	e Identifier (UDI) #			_	
Expiry	/ Date				
	someone operating the cal device when the problem red?				
For impla	anted medical devices O	NLY (such as pacemaker	rs, breast implants, etc.)		
Date the	implant was put in		Date the implant was taken ou relevant)	ıt (If	
Section [	O - About the Person Wh	no Had the Problem			
Perso	n's Initials	Unspecified			
Sex					
Age (	specify unit of time for age)				
Date	of Birth				
Weigh	nt				
Ethnic	city (Choose only one)				
Race	(Check all that apply)	American Indian or Alaskan Na Native Hawaiian or Other Pacif Asian White Black or African American			
List knov	vn medical conditions (S	uch as diabetes. high blo	od pressure, cancer, heart	disease. or others)	
	(-		p		
Please li	st all allergies (such as t	o drugs, foods, pollen or o	others)		
List any	other important informat	ion about the person (suc	h as smoking, pregnancy, a	alcohol use, etc.)	

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Lis	st all current prescription medications and medical devices being used.	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
$\mathbb{Q}_{\mathcal{L}}$	action E - About the Person Filling Out This Form	

tion E - About the Person Fil	ling Out This Form	1 of 1
Primary?	Yes	 
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		 
First name	(b) (6)	
Number/Street		
City		
State/Province		 
Country	USA	
ZIP or Postal code		
Telephone number	(b) (6)	
Email address		
Fax		
Reporter Organization		
Department		
Reporter Speciality		 
Today's date	14-Dec-2018	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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CTU No.: FDA-CDER-CTU-2019-42949 | Department: CFSAN | RCT No.: RCT-298450 | CTU Triage Date: 13-04-2019 | Total Pages

All dates displayed in the report are in EST(GMT-05:00) time zone

greatly.

Basic Details					
Company U		CDER-CTU	Originating Account	FAERS	
Source Med		MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority		Routine	Course Form Type	223 /2 33333	
-	ito Calculation Rule	No			
FDA Receiv		12-Apr-2019	CTU Received Date	12 <b>-</b> Apr-2019	
CTU Triage		12-Αμ1-2013	CTU Data Entry Date	12-74μ1-2010	
Report Type		Spontaneous	Report Classification	Drug	
Assign To	<del></del>	User	report Classification	Diug	
_		Usei			
User/Group					
Forward to	•	İ	SE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priorit	У	Direct			
Contact					
Case	First Name	Last Name	Email Address	Phone	
Reporter	(b) (6)	(b) (6)	(b) (6)	(b) (6)	
$\square$	(6) (0)	(5) (5)	(6) (6)	(b) (c)	
	Section A - About the Problem				
Section A -	· About the Problem				
What kir	nd of problem was it?	Were hurt or had a bad s	side effect (including new or worsening sympto	ms)	
What kir			side effect (including new or worsening sympto tly which could have or led to a problem	ms)	
What kir	nd of problem was it?		tly which could have or led to a problem	ms)	
What kir	nd of problem was it?	Used a product incorrect  Noticed a problem with t	tly which could have or led to a problem		
What kir (Check a	nd of problem was it?	Used a product incorrect  Noticed a problem with t	tly which could have or led to a problem he quality of the product		
What kir (Check a	nd of problem was it? all that apply)	Used a product incorrect  Noticed a problem with t  Had problems after switch	tly which could have or led to a problem he quality of the product		
What kir (Check a	nd of problem was it? all that apply)  problem occurred  of the following happen?	Used a product incorrect Noticed a problem with t Had problems after swite 18-Jan-2019 Yes	tly which could have or led to a problem he quality of the product ching from one product maker to another make		
What kir (Check a	nd of problem was it? all that apply) a problem occurred	Used a product incorrect Noticed a problem with t Had problems after swite 18-Jan-2019 Yes Hospitalization - admittee	tly which could have or led to a problem he quality of the product ching from one product maker to another make d or stayed longer		
What kir (Check a	nd of problem was it? all that apply)  problem occurred  of the following happen?	Used a product incorrect  Noticed a problem with t  Had problems after swite  18-Jan-2019  Yes  Hospitalization - admitted  Required help to prevent	tly which could have or led to a problem he quality of the product ching from one product maker to another make  d or stayed longer t permanent harm		
What kir (Check a	nd of problem was it? all that apply)  problem occurred  of the following happen?	Used a product incorrect Noticed a problem with t Had problems after swite 18-Jan-2019 Yes Hospitalization - admittee	tly which could have or led to a problem he quality of the product ching from one product maker to another make  d or stayed longer t permanent harm		
What kir (Check a	nd of problem was it? all that apply)  problem occurred  of the following happen?	Used a product incorrect  Noticed a problem with t  Had problems after swite  18-Jan-2019  Yes  Hospitalization - admittee  Required help to prevent  Disability or health problems	tly which could have or led to a problem he quality of the product ching from one product maker to another make  d or stayed longer t permanent harm		
What kir (Check a	nd of problem was it? all that apply)  problem occurred  of the following happen?	Used a product incorrect  Noticed a problem with t  Had problems after swite  18-Jan-2019  Yes  Hospitalization - admittee  Required help to prevent  Disability or health problem  Birth defect	tly which could have or led to a problem he quality of the product ching from one product maker to another make  d or stayed longer t permanent harm		
What kir (Check a	nd of problem was it? all that apply)  problem occurred  of the following happen?	Used a product incorrect Noticed a problem with t Had problems after swite 18-Jan-2019  Yes Hospitalization - admittee Required help to prevent Disability or health problem Birth defect Life-threatening Death	tly which could have or led to a problem he quality of the product ching from one product maker to another make  d or stayed longer t permanent harm		
Date the Serious Did any (Check a	nd of problem was it? all that apply)  problem occurred  of the following happen? all that apply)	Used a product incorrect Noticed a problem with t Had problems after swite 18-Jan-2019  Yes Hospitalization - admittee Required help to prevent Disability or health problems Birth defect Life-threatening Death Other serious/important wit happened (Included)	tly which could have or led to a problem he quality of the product ching from one product maker to another make  d or stayed longer t permanent harm em	г	
Date the Serious Did any (Check a	nd of problem was it? all that apply)  problem occurred  of the following happen? all that apply)  hat happened and how nal documents if necestreatment / Product- Kerat	Used a product incorrect Noticed a problem with t Had problems after swite 18-Jan-2019 Yes Hospitalization - admittee Required help to prevent Disability or health proble Birth defect Life-threatening Death Other serious/important w it happened (Includessary) tin Complex. ( https://www	tly which could have or led to a problem the quality of the product ching from one product maker to another make d or stayed longer t permanent harm em  medical incident(Please Describe Below) le as many details as possible F w.keratincomplex.com ) Jan 18th, 20	DA may reach out to you for	
Date the Serious Did any (Check a	nd of problem was it? all that apply)  problem occurred  of the following happen? all that apply)  hat happened and how nal documents if necestreatment / Product- Keratalong my hairline, face an	Used a product incorrect Noticed a problem with t Had problems after swite 18-Jan-2019  Yes Hospitalization - admittee Required help to prevent Disability or health problems Birth defect Life-threatening Death Other serious/important  w it happened (Includessary)  tin Complex. ( https://www.ind.neck, looked like chem.	tly which could have or led to a problem he quality of the product ching from one product maker to another make d or stayed longer t permanent harm em  medical incident(Please Describe Below) le as many details as possible F	DA may reach out to you for 119. Next day i wake up to a ehyde. Each time I washed	

rash all along my hairline, face and neck, looked like chemical burns. Stylist swore no Formaldehyde. Each time I washed hair, blow dried and used flat iron, rash would come back. I figured I was allergic to something else in it. Fast forward to March 2019, I am still getting the rash when I apply heat to my hair. Nose Bleeds. TONS of hair breakage. On April 5th, I am now seeing a pulmonologist for difficulty in breathing, heavy tight chest. I am on two different asthma inhalers. Finally asked my stylist for a list of ingredients. Boom, there it is- Timonacic... when heated such as for these treatments it turns into Formaldehyde. It wrecks HAVOC on skin and lungs. This is why every time I would wash, blow dry and flat iron my hair the rash would come back, heat brings it alive again. Chest Xray next week to see how much damage it has done to my pulmonary system, I am devastated. These companies LIE!!!!! They use different words to hide what is really in it. I do not blame my stylist, she was misinformed by this company saying no Formaldehyde. I am 46 years old and this has effected me

Re	elevant Test/Laboratory Data	1 of 1		
	Test Name		Test Date	

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	Test Result		Test Unit			
	Low Test Range		High Test Range			
	More Information Available?					
Ad	ditional Comments					
Se	ction B - Product Availability					
	Do you still have the product in	No				
	case we need to evaluate it?					
	Do you have a picture of the product? (check yes if you are	Yes				
	including a picture)				<u></u>	
Se	ction C - About the Products			1 of 1		
	Suspect	Yes				
	Primary?	Yes				
	Туре	Drug/Biologic				
	This report is about	Cosmetic, Dietary Suppleme	ent or Food/Medicinal Food		<u> </u>	
	Name of the product as it appears on the box, bottle,	KeratinComplex				
	or package (Include as many					
	names as you see)	https://www.kor.otingoppoles				
	Name of the company that makes (or compounds) the product	https://www.ker atincomplex.com /				
	Product Type(check all that	Over-the-Counter				
	apply)	Compounded by a Pharmacy of	or an Outsourcing Faci <b>l</b> ity			
		Generic				
	0	Biosimilar	It Ou			
	Strength		If Other			
	NDC number  Did the problem stop after the	No				
	person reduced the dose or	NO				
	stopped taking or using the product?					
	Did the problem return if the	Doesn't Apply				
	person started taking or using the product again?					
Dr	ug Therapy			1 of 1		
	Expiration date					
	Lot number					
	Dosage Form					
	Quantity		If Other			
	Frequency		If Other		<u> </u>	
	How was it taken or used	Other	If Other	hair	I	

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CTU No.: FDA-CDER-CTU-2019-42949 | Department: CFSAN | RCT No.: RCT-298450 | CTU Triage Date: 13-04-2019 | Total Pages

Date the person first started taking or using the product	18-Jan-2019		
Date the person stopped taking or using the product	18-Jan-2019		
Give best estimate of duration			
Is therapy still on-going?	Yes		
Why was the person using the p	roduct? (such as what c	ondition was it supposed to tre	at) 1 of 1
Hair smoothing			
Returned to Manufacturer On			
Section D - About the Medical De	evice		
Name of medical device			
Name of the company that makes the medical device			
Other identifying information (Th	e model, catalog, lot, se	rial, or UDI number, and the ex	piration date, if you can
locate them)			
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem occurred?	)		
For implanted medical devices C	NLY (such as pacemak	ers, breast implants, etc.)	
Date the implant was put in		Date the implant was taken out ( relevant)	If
Section E - About the Person Wh	no Had the Problem		
Person's Initials	(b) (6)		
Gender	Female		
Age (specify unit of time for age)	46 Year(s)		
Date of Birth			
Weight	50.4 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaskan  Native Hawaiian or Other Pa  Asian  White		

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CTU No.: FDA-CDER-CTU-2019-42949 | Department: CFSAN | RCT No.: RCT-298450 | CTU Triage Date: 13-04-2019 | Total Pages

	Black or Afr	rican American	
List known medical conditi	ons (Such as diabe	etes high blood pressure	cancer, heart disease, or others)
			hma, rashes and breathing issues since using
Please list all allergies (suc	ch as to drugs, foo	ds pollen or others)	
Cats, dogs, mold, grass, tr			
<del></del>		• •	g, pregnancy, alcohol use, etc.)
Past smoker, quit 5 1/2 ye	ars ago. Chest Xray-	taken April 2011 for surgery ar	nd was clear.
List all current prescription	medications and r	nedical devices being use	d.
Symbacort, Albuteral			
List all over-the-counter me	edications and any	vitamins, minerals, supple	ements, and herbal remedies being used.
Allegra D			
Section F - About the Pers		Form	1 of 1
Primary?	Yes		
Reporter is Patient?			
Title	(1) (2)		
Last name	(b) (6)		
Middle Name			
First name	(b) (6)		
Number/Street	(b) (6)		
City	(b) (6)		
State/Province	(b) (6)		
Country	USA		
ZIP or Postal code	(b) (6)		

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(b) (6)

(b) (6)

Telephone number

Email address

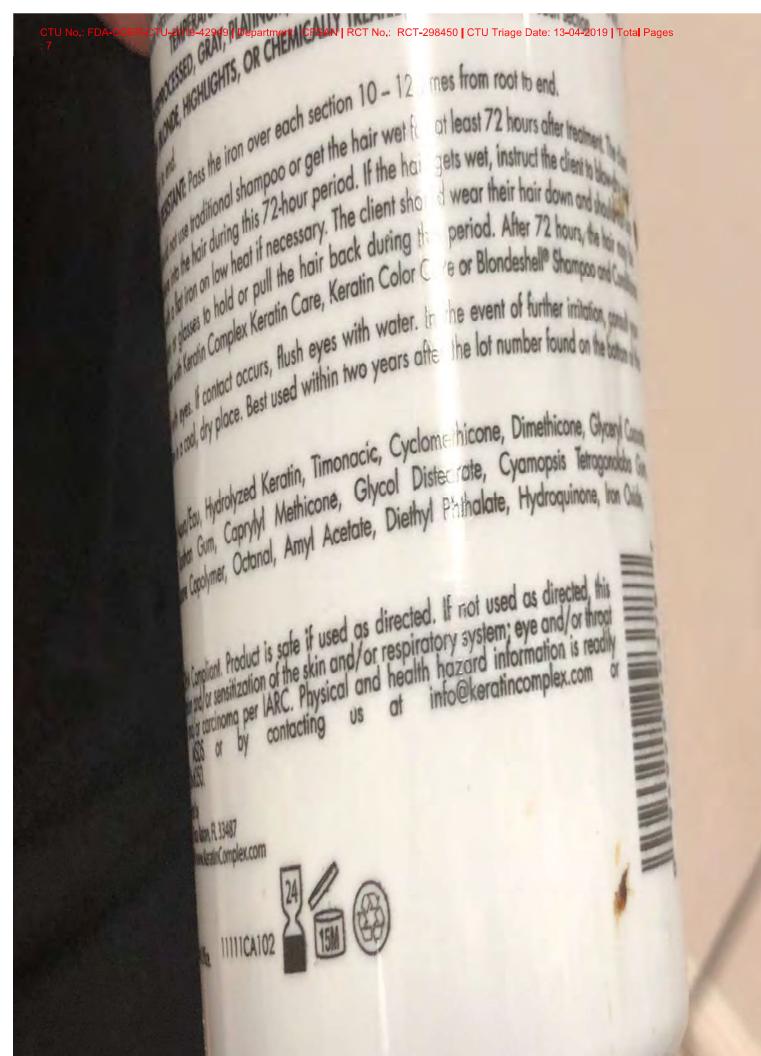
Fax

CTU No.: FDA-CDER-CTU-2019-42949 | Department: CFSAN | RCT No.: RCT-298450 | CTU Triage Date: 13-04-2019 | Total Pages

Reporter Organization		
Department		
Reporter Speciality		
Today's date	12-Apr-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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## (b) (6)



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All	dates r	lienlave	d in the	report	are in	EST	CMD	(-05:00)	time	zone
7311	Gales C	H2DIGAC:	A III HIE	1 CDOH	are II	15311	13IVI	-05.001	HILLS	ZOHE.

asic Deta	ails		-0757777	CANADA IN CO.			
company l	Jnit	CDER-CTU	Originating Account	FAERS			
Source Medium		MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority		Routine	Routine				
verride A	uto Calculation Rule	No					
DA Recei	ved Date	24-May-2019	CTU Received Date	24-May-2019			
TU Triage	e Date		CTU Data Entry Date				
Report Typ	oe .	Spontaneous	Report Classification	Drug			
ssign To		User		,			
Jser/Group	p						
orward to	Department	CDER (CDER-C	OSE-RSS-CTU@fda.hhs.gov) (E2B)				
ase Prior	ity	Direct	3, (,				
ontact							
ase leporter	First Name	Last Name	Email Address	Phone			
<b>a</b>	(b) (6)						
	- About the Problem						
	e problem occurred		ritching from one product maker to another make				
Serious		Yes					
	of the following happen? all that apply)	Hospitalization - admitt Required help to preve Disability or health prol Birth defect Life-threatening Death	ent permanent harm blem				
	what happened and how onal documents if nece	w it happened (Inclu	nt medical incident(Please Describe Below) ide as many details as possible F	DA may reach out to you fo			
with wir		" A week later, I have b	any potential side effects, but day of lolisters on my neck and forehead, and				
1			Test Data	1 01 1			
Test Na	anie		Test Date				
Test Re	esult		Test Unit				
Low Te	st Range		High Test Range				
Mari	formation Available?		4	4.5			

CTU No.: FDA-CDER-CTU-2019-60721 | Department: CFSAN | RCT No.: RCT-376450 | CTU Triage Date: 25-05-2019 | Total Pages

Ac	Iditional Comments		
Se	ection B - Product Availability		
	Do you still have the product in case we need to evaluate it?	No	
	Do you have a picture of the product? (check yes if you are including a picture)	No	
Se	ection C - About the Products		1 of 1
	Suspect	Yes	
	Primary?	Yes	
	Туре	Drug/Biologic	
	This report is about	Cosmetic, Dietary Supplement or Food/Med	icinal Food
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout	
	Name of the company that makes (or compounds) the product		
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Fa Generic Biosimilar	cility
	Strength	If Other	
	NDC number	, , , , , , , , , , , , , , , , , , ,	
	Did the problem stop after the person reduced the dose or stopped taking or using the product?		
	Did the problem return if the person started taking or using the product again?		
וטן	ug Therapy  Expiration date		1 of 1
	Lot number		
	Dosage Form		
	Quantity	If Other	
	Frequency	If Other	
	How was it taken or used	If Other	
	Date the person first started	11 00101	
	taking or using the product		
	Date the person stopped taking or using the product		
	Give best estimate of duration	-	

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	Is therapy still on-going?				
\/\/b	y was the person using the pr	oduct? (such as what cor	ndition was it supposed to t	reat) 1 of 1	
7	ry was the person using the pr	oddot: (Sdori da Wildt Col	tarion was it supposed to t		
	Returned to Manufacturer On				
Sed	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Oth	ner identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the	expiration date, if you can	
	Model Number				
	Catalog Number				
	Lot Number			_	
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem occurred?			_	
For	· implanted medical devices O	NI V (such as pasamaka	re broast implants atal		
	ite the implant was put in	NET (Such as pacemake)	Date the implant was taken or relevant)	ut (If	
Sec	ction E - About the Person Wh	o Had the Problem			
	Person's Initials	(b) (6)			
	Gender	Female		_	
	Age (specify unit of time for age)	60 Year(s)			
	Date of Birth				_
	Weight	67.5 kg		_	
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaskan Na	ntive		
		Native Hawaiian or Other Pacit			
		Asian			
		White			
		Black or African American			

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

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