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

CIL	J No.: FDA-CDER-CTU-2019-60721	Department:	CESAN	RCT No.:	RCT-376450	1010
5						

	Fibromyalgia	
Ple	ease list all allergies (such as to drugs, foods, pollen or others)	
	Penicillin, shellfish	
Lis	t any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	t all current prescription medications and medical devices being used.	
	Valacyclovir 500 mg daily	
Lis	t all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	Probiotic, vitamin b complex, vitamin d, Alavert, tylenol	

ction F - About the Persor	Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		_
Last name	(b) (6)	_
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	_
City	(b) (6)	
State/Province		
Country	USA	_
ZIP or Postal code	(b) (6)	_
Telephone number	(b) (6)	
Email address	(b) (6)	_
Fax		
Reporter Organization		
Department		_
Reporter Speciality		

Generated by: SYSTEM Generated on: 24-May-2019 19:45:56 Page 4 of 5

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

: 5

Today's date	24-May-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 24-May-2019 19:45:56 Page 5 of 5

CTU No.: FDA-CDER-CTU-2019-79089 | Department: CFSAN | RCT No.: RCT-449968 | CTU Triage Date: 06-07-2019 | Total Pages

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

Basic Deta	ails							
Company U		CDER-CTU	Origi	nating Account	FAERS			
Source Me	dium	MWO (Drug)	Sour	ce Form Type	E2B XML 3500B			
Priority		Routine						
Override Auto Calculation Rule		No	No					
FDA Recei	ved Date	06 <b>-</b> Jul-2019	СТИ	Received Date	06 <b>-</b> Jul-2019			
CTU Triage	e Date		СТИ	Data Entry Date				
Report Typ	e	Spontaneous	Repo	ort Classification	Drug			
Assign To		User						
User/Group	)							
Forward to	Department	CDER (CDER-C	OSE-RSS-CT	U@fda.hhs.gov) (E2B)				
Case Priori	ity	Direct		<u> </u>				
Contact								
Case Reporter	First Name	Last Name		Email Address	Phone			
$\square$	(b) (6)	(b) (6)		(b) (6)	(b) (6)			
	- 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 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  O3-Jul-2019  Serious  Did any of the following happen? (Check all that apply)  Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)					I for			
any additio	4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)  I had a Keratin treatment applied at Hair Today in Norriston in Pennsylvania and it caused severe eye and nasal watering.							
Relevant T	Relevant Test/Laboratory Data 1 of 1							
Test Na	·		Test	Date				
Test Re			Test					
Low Tes	st Range		High	Test Range				
	formation Available?		1.1.911					

Generated by: SYSTEM Generated on: 06-Jul-2019 09:15:12 Page 1 of 5

CTU No.: FDA-CDER-CTU-2019-79089 | Department: CFSAN | RCT No.: RCT-449968 | CTU Triage Date: 06-07-2019 | Total Pages

٠	5

Ad	ditiona <b>l</b> Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?  Do you have a picture of the	No No			
	product? (check yes if you are including a picture)				
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		_
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Keratin Hair Treatment			
	Name of the company that makes (or compounds) the product				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar	or an Outsourcing Faci <b>l</b> ity		
	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			
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	02-Jul-2019			
	Date the person stopped taking or using the product	02-Jul-2019			
	Give best estimate of duration				

Generated by: SYSTEM Generated on: 06-Jul-2019 09:15:12 Page 2 of 5

CTU No.: FDA-CDER-CTU-2019-79089 | Department: CFSAN | RCT No.: RCT-449968 | CTU Triage Date: 06-07-2019 | Total Pages

	Is therapy still on-going?				-
W	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to t	reat) 1 of 1	
	Keratin Treatment				
	Deturned to Manufacturer On				_
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot loc	her identifying information (The cate them)	e model, catalog, lot, seri	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?				
Fο	r implanted medical devices C	NLY (such as pacemake	rs, breast implants, etc.)		
	ate the implant was put in	real (sas. as pass. and	Date the implant was taken ou	ut (If	
			relevant)		
Se	ction E - About the Person Wh	o Had the Problem			
	Person's Initials	(b) (6)			
	Gender	Female			
	Age (specify unit of time for age)	43 Year(s)			
	Date of Birth				
	Weight	74.25 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaskan Na	ative		
		Native Hawaiian or Other Paci	fic Islander		
		Asian			
		White			
		Black or African American			

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

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CTU No.: FDA-CDER-CTU-2019-79089 | Department: CFSAN | RCT No.: RCT-449968 | CTU Triage Date: 06-07-2019 | Total Pages

	Asthma and allergies	
Dle	ease list all allergies (such as to drugs, foods, pollen or others)	
1 10		
	Pollen, dust mites, mold and dog dander	
		<u></u>
Lis	t any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	t all current prescription medications and medical devices being used.	
	Fluticasone nasal spray and loratadine	
Lis	t all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	Vitamin D3, Omega 3, Magnesium, Iron and multi	

ction F - About the Perso	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		

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 $CTU\ No.:\ FDA-CDER-CTU-2019-79089\ |\ Department:\ CFSAN\ |\ RCT\ No.:\ RCT-449968\ |\ CTU\ Triage\ Date:\ 06-07-2019\ |\ Total\ Pages$ 

: 5

Today's date	06-Jul-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 06-Jul-2019 09:15:12 Page 5 of 5

 $CTU\ No.:\ FDA-CDER-CTU-2019-89010\ |\ Department:\ CFSAN\ |\ RCT\ No.:\ RCT-496785\ |\ CTU\ Triage\ Date:\ 31-07-2019\ |\ Total\ Pages$ 

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

Ba	Basic Details								
Company Unit		nit	CDE	R-CTU	Originating Account		FAERS		
S	ource Med	ium	MW	O (Drug)	Sour	ce Form Type	E2B XML 3500B		
Priority			Rou	Routine					
Override Auto Calculation Rule			No	No					
FI	DA Receiv	ed Date	31 <b>-</b> J	Jul-2019	CTU	Received Date	31 <b>-</b> Jul-2019		
C	TU Triage	Date			CTU	Data Entry Date			
R	eport Type	)	Spo	ntaneous	Repo	rt Classification	Drug		
A	ssign To		Use	r					
U:	ser/Group								
F	orward to I	Department	V	CDER (CDER-OSE-RS	SS-CTI	J@fda.hhs.gov) (E2B)			
С	ase Priorit	у	Dire	ct					
Co	ntact								
	ase eporter	First Name		Last Name		Email Address	Phone		
V	3	(b) (6)		(b) (6)		(b) (6)	(b) (6)		
		About the Problem							
	)	d of problem was it?							
		all that apply)	100	Were hurt or had a bad side effect (including new or worsening symptoms)					
				Used a product incorrectly which could have or led to a problem  Noticed a problem with the quality of the product					
			Had problems after switching from one product maker to another maker						
	Date the	problem occurred							
	Serious		Yes						
		of the following happen?			aved lon	aer			
	(Check a	all that apply)	Required help to prevent permanent harm						
			$\mathbf{Z}_{0}$	Disability or health problem					
			Birth defect						
				Life-threatening					
				Death					
	- 11			Other serious/important medica					
4. an	l ell us wi y additio	nat happened and how nal documents if nece	with essary	appened (Include as y)	many	∕ details as possible FDA r	may reach out to you for		
						by Brazilian blowout. My docto	ors currently think that my		
	inflamed	liver has been a result of	my ir	nnalation of the formalde	enyae 1	rumes from this product			
Re	Relevant Test/Laboratory Data 1 of 1								
	Test Nar	me			Test	Date			
	Test Res	sult			Test	Unit			
	Low Tes	t Range			High	Test Range			
	More Inf	ormation Available?							

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CTU No.: FDA-CDER-CTU-2019-89010 | Department: CFSAN | RCT No.: RCT-496785 | CTU Triage Date: 31-07-2019 | Total Pages

Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes	_		
	Туре	Drug/Biologic			
	This report is about				
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout .smooth	ritual . Uberliss. Keratin complex	. Express	
	Name of the company that makes (or compounds) the product	Brazilian blowout.Uberlis s	. coppol		
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic Biosimilar	or an Outsourcing Faci <b>l</b> ity		
	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			
Dr	ug Therapy			1 of 1	
	Expiration date			_	
	Lot number		_		
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Respiratory (inhalation)	If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Give best estimate of duration				

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CTU No.: FDA-CDER-CTU-2019-89010 | Department: CFSAN | RCT No.: RCT-496785 | CTU Triage Date: 31-07-2019 | Total Pages

Is therapy still on-going?						
Why was the person using the p	 roduct? (such as what co	ndition was it supposed to	treat) 1 of 1			
The the person doing the p	- Casil as what col	ramon was a supposed to				
Returned to Manufacturer On						
Treturned to Mandiacturer On						
Section D - About the Medical D	evice					
Name of medical device						
Name of the company that makes the medical device						
Other identifying information (Th locate them)	e model, catalog, lot, seri	al, or UDI number, and the	e 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 problen occurred?	1					
For implanted medical devices (	)NLY (such as nacemake	rs breast implants etc.)	_			
Date the implant was put in	711E1 (Saon as pasemake	Date the implant was taken	out (If			
, ,		relevant)	,			
Section E - About the Person W	ho Had the Problem					
Person's Initials	(b) (6)					
Gender	Female					
Age (specify unit of time for age)	47 Year(s)					
Date of Birth		-				
Weight	61.2 kg					
Ethnicity (Choose only one)	Not Hispanic/Latino					
Race (Check all that apply)	American Indian or Alaskan Na	ative				
	Native Hawaiian or Other Paci					
				1		
	Asian White					

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

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CTU No.: FDA-CDER-CTU-2019-89010 | Department: CFSAN | RCT No.: RCT-496785 | CTU Triage Date: 31-07-2019 | Total Pages

	Autoimmune hepatitis Nash	
Ple	ease list all allergies (such as to drugs, foods, pollen or others)	
	Penicillins Omnicef Tequiin Macrobid Mango Surgical adhesive	
l ic	t any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
LIS	None	
	None	
Lis	t all current prescription medications and medical devices being used.	
	Hydroxizine allergy med	
Lic	t all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
LIS		
	Probiotic	

tion F - About the Person	Yes	1 of 1
Primary?	res	
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	UNITED STATES	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		

Generated by: SYSTEM Generated on: 31-Jul-2019 17:45:06 Page 4 of 5

CTU No.: FDA-CDER-CTU-2019-89010 | Department: CFSAN | RCT No.: RCT-496785 | CTU Triage Date: 31-07-2019 | Total Pages

Today's date	31-Jul-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 31-Jul-2019 17:45:06 Page 5 of 5

Page 2 of 3 2019-08-26 10:26:45 (GMT) CTU No.: FDA-CDER-CTU-2019-100428 | Department: CFSAN | RCT No.: RCT-543648 | CTU Triage Date: 28-08-2019 | Total Page Form Approved: OMB No. 0910-0291, Expires: 9/30/2018

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

FORM FDA 3500A (10/15)

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

Page 1 of---2----

See PRA statement on rever	DU.
Mfr Report#	7
US-JNJF0C-20190820522	- 1
UF/Importer Report#	
10 10 10 10 X	7

					FDA Use Only
Note: For date prompts of "dd-n		figit day, 3-letter month	3. Dose	Frequency	Route Used
<ul> <li>abbreviation, and 4-digit year, for A. PATIENT INFORMATION</li> </ul>			#1 1		Topical
Patient Identifier   2. Age	Year(s) Month(s	3. Sex 4. Weight	100		
· ·	☐ Week(s) ☐ Day(s)	' l	#2		
(b) (6)		X Female	4. Thurston Dates //	unknown give duration) from/	9. Event Abated After Use
in Confidence (b)	f Birth <i>(e.g., 08 Feb 1925</i> <b>(6)</b>	Male Dib	to (or best estima	te) (da-anmm-yyyy)	Stopped or Dose Reduced?
	Race (Check all that appl		#1		#1 Yes No X Doesn' apply
m/m m/m the set assessment with	sian American indi	**	#2		
press 1	lack or African American lative Hawaiian or Other I	☐ White Pacific Islander	5. Diagnosis for Us #1 UNKNOWN I		#Z Yes No Doesn' apply
B. ADVERSE EVENT OF	PRODUCT PROBL	EM	#2		10. Event Reappeared After Reintroduction?
Adverse Event and/or	Product Problem	e.g., defects/malfunctions)			#1 Yes No X Doesn'
2. Outcome Attributed to Adve	rse Event (Check all tha	t apply)	6. Is the Product	7. Is the Product Over	
Death Include date (dd-m	rnm-yyyy):		Compounded ?	the-Counter?	#2 Yes No Doesn'
Life-threatening		or Permanent Damage	#1 Yes N		apply
☐ Hospitalization - initial or pr  X Other Serious (Important M		tal Anomaly/Birth Defects	#2 Yes N	LI 100 LI 110	
Required Intervention to Pro		ent/Damage (Devices)	6. Expiration Date	dd-mmm-yyyy) #2	
		Report (dd-inmin-yyyy)	G. ALL MANUF	0.000	
3. Date of Event (dd-mmm-yyy	25-Aug-1	THE R. P. LEWIS CO., LANSING MICH. 400, LANSING MICH. 400, LANSING MICH. 400, LANSING MICH. 400, LANSING MICH.	Contract of the Contract of th	Manufacturing Site for Devices)	2. Phone Number
5. Describe Event or Problem	23 Aug".		Name TNT Communication	r US Cosmetic	732-754-2672
This spontaneous from a patient co of unspecified ag The patient's wei medical bistory w	ncerned a fema e. ght, height, a	and	Address OCMS 199 Grandvi Skillman,NJ	ew Road	3. Report Source (Check all that apply)  Foreign
The patient recei	ved OGX EVER			Continu	red Study
STRAIGHTENING BRA	ZILIAN KERATII		Email Address	1	Literature
C. Balarent Tantali abayatayı (	Nata Institution Dates	Continued	ngami@its.j		X Consumer
6. Relevant Tests/Laboratory I	ata, including Dates		Compounding Outsourd		Health Professional
			Date Received by     Manufacturer (dd-nm)	5. NDA#	User Facility
			15-Aug-20	# ACIMA	Company Representative
				# O/#	Distributor
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		~~****	6. If IND, Give Protoco		Other:
<ol><li>Other Relevant History, Incli- allergies, pregnancy, smoking</li></ol>				PMA/ 510(k) #	_
		,	7. Type of Report		
			(Check all that apply)	Product	95
			5-day <b>X</b> 30-da	ry	
			7-day Perio	t t	
C. SUSPECT PRODUCT			10-day X Initin	ore (1)	hes
Name, Manufacturer/Compo      Name and Strength	under, Strength	#1 - NDC # or Unique ID	15-day Follo	<b>∿</b> -up #	
OGX EVER	Continued	F) - NDC F G CIRGUE ID	9. Manufacturer Repor	Number 8 Adverse Event	Term(s)
#1 - Manufacturer/Compounder		#1 - Lot#	OS-JEJFEC-20190	820522 1) FORMAL (Chemi	Tem(s) DEHYDE POISONING cal poisoning
#2 - Name and Strength		40 NDC 4 actions in		(10008	428), Chemical Continued
We - Leaning with Shapifiles		#2 • NDC # or Unique ID	E. INITIAL REPO	ORTER	Continued
#2 - Manufacturer/Compounder		#2 - Lot#	1. Name and Address		Continued
			Last Name; (b) (6)		Name:(b) (6)
2. Concomitant Medical Produ	Contract of the Contract of th	Exclude treatment of event)	Address : (0) (6)		North North North National North Nor
Concomitant Druge	Not Reported		City:(b)(6)	State/Prov	IncerRegion:
			Country USA		Postal Code (b) (6)
			Prione #:	Email: (b) (	6)
Submission of a report doe	es not constitute an a	dmission that medical	2. Health	3. Occupation	4. Initial Reporter Also Sent
personnel, user facility, imp caused or contributed to the		nufacturer or product	Professional?	Patient	Report to FDA
caused or contributed to th	e event.				

Date of This Report: 25-Aug-2019

#### B. ADVERSE EVENT OR PRODUCT PROBLEM

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

THERAPY CONDITIONER UNSPECIFIED (shampoo, topical, batch number not reported) dose, THERAPY CONDITIONER UNSPECIFIED (snampoo, topical, patch number not reported) dose, frequency, and therapy dates not reported, for unknown indication. No concomitant medications were reported. On an unspecified date, 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 product ingredient issue was reported.

The action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER UNSPECIFIED was not reported. The patient had not recovered from formaldehyde poisoning, hair loss and formaldehyde pockets in gums. The outcome for product ingredient issue was not reported. This report was serious (Other Medically Important Condition). This report was associated with a product quality complaint: 30001580043.

#### Company Remarks:

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

Seq No. : 1

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

CONDITIONER

C.9 Dechallenge :2) N/A

:3) N/A :4) N/A

C.10 Rechallenge

:2) N/A:3) N/A

:4) N/A

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

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) FORMALDEHYDE FOISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
- 2) hair loss (Application site alopecia (10059046), Application site alopecia (10059046))
  3) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))
  4) PRODUCT INGREDIENT ISSUE (Product ingredient issue (10071303), Product formulation

issue (10069228))

Page 2 of 3 2019-08-29 05:41:45 (GMT) CTU No.: FDA-CDER-CTU-2019-101858 | Department: CFSAN | RCT No.: RCT-549098 | CTU Triage Date: 02-09-2019 | Total Page Form Approved, OMB No. 0910-0291, Excires. 9/30/2018 See PRA statement on reverse. U.S. Department of Health and Human Services For use by user-facilities, Mfr Report # Food and Drug Administration importers, distributors and manufacturers US-JNJF0C-20190820522 MEDWATCH for MANDATORY reporting UF/Importer Report # FORM FDA 3500A (10/15) Page 1 of 2 FDA Use Only Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month 3. Dose Route Used Frequency abbreviation, and 4-digit year, for example, 01-Jul-2015. Topical #1 A. PATIENT INFORMATION 1. Patient Identifier | 2. Age 4. Weight Year(s) Month(s) #2 Week(s) Day(s) (b) (f) X Female 4. Therapy Dates (If unknown give duration) from/ ☐ lb 9. Event Abated After Use (325) Male to (or best estimate)) (dd-minin-yyyy) Stopped or Dose Reduced? In Confidence □ Ka "nased X DN seY T 5,a, Ethnicity (Check 5,b, Race (Check all that apply) apply #2 single best answer) Asian American indian or Alaskan Native 5. Diagnosis for Use (Indication) Yes No Doesn't Hispanic/Latino 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 Reintroduction? Product Problem (e.g., defects/malfunctions) X Adverse Event and/or #1 Yes No X Doesn't 2. Outcome Attributed to Adverse Event (Check all that apply) ි. is the Product 7. Is the Product Over-Compounded? the-Counter? Death Include date (dd-mmm-yyyy) : #2 Yes No 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 X Other Serious (Important Medical Events) 8. Expiration Date (dd-mmm-yyyy) #2 Required Intervention to Prevent Permanent Impairment/Damage (Devices) #1 G. ALL MANUFACTURERS 3 Date of Event (dd-mmm-yyyy) 4 Date of this Report (dd-mmm-yyyy) 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number 27-Aug-2019 732-754-2672 Name 5. Describe Event or Problem Consumer US Cosmetic JNJ 3. Report Source This spontaneous report received Address from a patient concerned a female of unspecified age. (Check all that apply) OCMS 199 Grandview Road The patient's weight, height, and medical history were not reported. The patient received OGX EVER Foreign Skillman, NJ Study Continued STRAIGHTENING BRAZILIAN KERATIN Literature Email Address Continued ngami@its.jnj.com X Consumer 6. Relevant Tests/Laboratory Data, including Dates Yes Compounding Outsourcing Facility 503B? Health Professional 4. Date Received by User Facility NDA# Manufacturer (dd-mmm-yyyy) Company ANDA#

 Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) C. SUSPECT PRODUCT(S) 1. Name, Manufacturer/Compounder, Strength #1 - NDC # or Unique ID #1 - Name and Strength OGX EVER Continued #1 - Manufacturer/Compounder #1 - Lot# #2 - Name and Strength #2 - NDC # or Unique ID #2 - Manufacture:/Compounder #2-Lot# 2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) Concomitant Drugs Not Reported

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.

15-Aug-2019 Representative IND# Distributor A A 6. If IND, Give Protocol # Other PMA 510(k) # 7. Type of Report Combination (Check all that apply) Product Yes X 30-day 5-day Pre-1938 Yes Periodic OTC: Yes X Infial income 13-day Follov-up #\_ 8. Adverse Event Tenn(s)
1) FORMALDEHYDE POISONING 9. Manufacturer Report Number DS-JNJF087-20190820522 Chemical poisoning (10008428), Chemical Continued E. INITIAL REPORTER 1. Name and Address Continued = rst Name (b) (6) Last Name (b) (6) Address (b) (6) City (b) (6) State/Province/Region Country: USA ZIP/Postal Code: (b) (6) Email: (b) (6) Phone # 4 Initial Reporter Also Sent Report to FDA ≥ Healtfa 5 Occupation Professional? Patient Yes X No Yes No Unk

Date of This Report: 27-Aug-2019

#### B. ADVERSE EVENT OR PRODUCT PROBLEM

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

THERAPY CONDITIONER UNSPECIFIED (shampoo, topical, batch number not reported) dose, frequency, and therapy dates not reported, for unknown indication. No concomitant medications were reported. On an unspecified date, 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 product ingredient issue was reported. The product label had improper directions (product label issue)

The action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER UNSPECIFIED was not reported. The patient had not recovered from formaldehyde poisoning, hair loss and formaldehyde pockets in gums. The outcome for product ingredient issue and product label issue was not reported. This report was serious (Other Medically Important Condition) This report was associated with a product quality complaint: 30001580043.

Version created to amend previously reported information on 15-AUG-2019. Upon review, the following information was amended: event details (product label issue).

#### Company Remarks:

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

Seq No. C.I Suspect Product :OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER C.9 Dechallenge :2) N/A:3) N/A :4) N/A :5) N/A C.10 Rechallenge :2) N/A :3) N/A :4) N/A :5) N/A

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

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) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
  2) hair loss (Application site alopecia (10059046), Application site alopecia (10059046))
  3) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))
  4) PRODUCT INGREDIENT ISSUE (Product ingredient issue (10071303), Product formulation
- issue (10069228))

5) IMPROPER DIRECTIONS (PRODUCT LABEL ISSUE) (Product label issue (10069289), Product label issue (10069289))

CTU No.: FDA-CDER-CTU-2019-106002 | Department: CFSAN | RCT No.: RCT-570785 | CTU Triage Date: 13-09-2019 | Total Page Form Approved: OMB No. 0910-0291, Expires: 9/30/2018 0.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 2

Seo PRA st	latoment on n	OVOISU.
Mfr Report# -US-JNJFOC-20190820522		
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Product Pounded ?  Yes No No In No Yes No	(Indication)  (Indication)  (Indication)  IDICATI  7. Is the the #1 [ #2 [ d-main-yyy)  CTURERS anufacturing  #3. US Co	o duration) from/ -yyyy)  ON  the Product Over- Counter?  Yes No Yes No y)  #2 S Site for Devices)  smetic	Popical  9. Event Abated After Use Stopped or Dose Reduced? #1
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Product pounded?  Yes No Yes No Tation Date (or Consumer Grandvie Iman, NJ	7. Is the the #2 [ CTURERS anufacturing #2 CO	on he Product Over-Counter? Yes No Yes No #2 Site for Devices	apply  10. Event Reappeared After Reintroduction? #1  Yes  No  Doesn apply  #2  Yes  No  Doesn apply  2. Phone Number  732-754-2672 3. Report Source (Check aft that apply)  Foreign
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Date of This Report: 08-Sep-2019

#### B. ADVERSE EVENT OR PRODUCT PROBLEM

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

THERAPY CONDITIONER UNSPECIFIED (shampoo, topical, batch number not reported) dose, frequency, and therapy dates not reported, for unknown indication. No concomitant medications were reported. On an unspecified date, 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. gums which were not going away.
The action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER UNSPECIFIED was not reported. The patient had not recovered from formaldehyde poisoning, hair loss and formaldehyde pockets in gums. This report was serious (Other Medically Important Condition).

Version created to amend previously reported information on 15-AUG-2019. Upon review, the following information was amended: event details (product label issue).

Additional information was received from patient on 15-AUG-2019. Upon review, the following information was amended: event of product ingredient issue and product label issue removed.

#### Company Remarks:

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

Seq No. : 1

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

CONDITIONER

C.9 Dechallenge :2) N/A :3) N/A

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

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

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)

- FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
   hair loss (Application site alopecia (10059046), Application site alopecia (10059046))
   FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))

caused or contributed to the event.

CTU No.: FDA-CDER-CTU-2019-108138 | Department: CFSAN | RCT No.: RCT-578831 | CTU Triage Date: 18-09-2019 | Total Page

Form Approved. OMB No. 0910-0291, Expires: 9/30/2018 U.S. Department of Health and Human Services See PRA statement on reverse. For use by user-facilities, Food and Drug Administration Mfr Report # importers, distributors and manufacturers US-JNJFOC-20190820522 MEDWATCH for MANDATORY reporting UF/Importer Report # FORM FDA 3500A (10/15) Page 1 of 2 FDA Use Only Note: For date prompts of "ad-mmm-yyyy" please use 2-digit day. 2-tetter month Совя Route Used Frequency abbreviation, and 4-digit year, for example, 01-Jul-2015. Topical #1 A. PATIENT INFORMATION 1. Patient Identifier 2. Age Year(s) Month(s) 4. Weight #2 ☐ Week(8) ☐ Day(s) (b) (6) X Female or Dato of Birth (e.g., 08 Feb 1926) Therapy Dates (If unknown give duration) from/ to (or bost estimate)) (od-mmm-yyyy) 9 Event Abated After Use ☐ Male Stopped or Dose Reduced? In Confidence ☐ ka #1 #1 Yes No Z Doesn't 5.a. Ethnicity (Check single best answer) 5.b. Race (Check all that apply) Asian American indian or Alaskan Native 5. Diagnosis for Use (Indication) #2 Yes No Doesn't ☐ Hispanic/Latino ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander #1 UNKNOWN INDICATION Not Hispanic/Latino 10 Event Reappeared After Reintroduction? B ADVERSE EVENT OR PRODUCT PROBLEM 43 Product Problem (e.g., defects/melfunctions) 1. X Adverse Event andior #1 Yes No X Doesn't 2. Outcome Attributed to Adverse Event. (Check all that apply) 6. le the Product 7. is the Product Over-Compounded ? the-Counter? Death include date (dd-mmm-yyyy) : #2 🔲 Yes 🔲 No 🛄 Doesn't Yes No Yes No Life-threatening Disability or Permanent Damage Mospitalization - Intital or prolonged Congenital Anomaly/Birth Defects CN D seY #2 Yes No Dither Serious (Important Medical Events) 6. Expiration Date (do-mmm-yyyy) #2 Required Intervention to Prevent Permanent Impairment/Damage (Devices) #1 G ALL MANUFACTURERS 3. Date of Event (ad-mmm-yvvv) 4. Date of this Report (dd-renm-yyyy) 1. Contact Office (and Mercufacturing Site for Devices) 2. Phone Number 14-Sep-2019 Name 732-754-2672 5. Describe Event or Problem JNJ Consumer US Cosmetic 3. Report Source This spontaneous report received from a patient concerned a female Address (Check all that apply) OCMS of unspecified age. 199 Grandview Road Skillman, NJ The patient's weight, height, and medical history were not reported. The patient received OGX EVER STRAIGHTENING BRAZILIAN KERATIN Foreign Study Continued Literature Email Address Continued ngami@its.jnj.com XI Consumer 6. Relevant Tests/Laboratory Date, including Dates Compounding Outsourcing Facility 5038? Yes Health Professional 4. Date Received by User Facility NDA# Manufacturer (dd-mmm-yyyy) Company Company ANDA# 15-Aug-2019 Representative IND # Distributor 6. If IND, Give Protocol# Other: Other Relevant History, Including Preoxisting Medical Conditions (e.g., allergies, pregnancy, smaking and alcohol use, liver/kidney problems, etc.) PMA 510(k)# 7, Type of Report (Check all that apply) Combination Product Yes X 30-day δ-day Pre-1938 T Yes 7-day Periodic OTC Ves C SUSPECT PRODUCTISE 10 day | Initial 1. Name, Manufacturer/Compounder, Strength 15-day X Follow-up # ..... #1 - NDC # or Uniose to #1 - Name and Strength OGX EVER Continued 6. Adverse Event Term(s)
1) FORMALDEHYDE POISONING 9. Manufacturer Report Number #1 - Manufacturer/Compounder #1 - LOT# US-TESTFOC-20190620522 (Chemical poisoning (10008428), Chemical Continued #2 - Name and Strength #2 - NDO # or Unique ID E. INITIAL REPORTER #2 - Manufacturer/Compounder #2 - Lot# 1. Name and Address Continued Lust Name: (b) (6) First Name (b) (6) 2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) Address (B) (6) Concomitant Drugs Not Reported city:(b)(6) State/Province/Region (b)(6)ZIP/Postal Code : Country USA Empli (b) (6) Phone # Submission of a report does not constitute an admission that medical 3 Occupation 4. Initial Reporter Also Sent 2 Health Professional? Report to FDA personnel, user facility, importer, distributor, manufacturer or product Patient Yes X No ☐ Yes ☐ No ☐ Unk

4/09/19 18:44 SCIFORMIX 912067952109 Page 2

CTU No.: FDA-CDER-CTU-2019-108138 | Department: CFSAN | RCT No.: RCT-578831 | CTU Triage Date: 18-09-2019 | Total Page

Continuation Sheet for FDA-3500A Form

Page 2 of 2

Mfr. Report #: US-JNJFOC-20190820522

Date of This Report: 14-Sep-2019

# B. ADVERSE EVENT OR PRODUCT PROBLEM

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

THERAPY CONDITIONER UNSPECIFIED (shampoo, topical, batch number not reported) dose, frequency, and therapy dates not reported, for unknown indication. No concomitant medications were reported. On an unspecified date, 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 action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER UNSPECIFIED was not reported. The patient had not recovered from formaldehyde poisoning, hair loss and formaldehyde This report was serious (Other Medically Important Condition),

Version created to amend previously reported information on 15-AUG-2019. Upon review, the following information was amended: event details (product label issue).

Additional information was received from patient on 15-AUG-2019. Upon review, the following information was amended: event of product ingredient issue and product label issue removed,

Additional information was received on 15-AUG-2019.
It has been determined that this case is a duplicate of Manufacturer Report Number 20180719747. This case (Manufacturer Report Number 20190820522) will be deleted. All relevant information regarding this case will be submitted under Manufacturer Report Number 20180719747.

#### Company Remarks:

. . .

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

C.9 Dechallenge

Seq No. C.1 Suspect Product

COCK EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY

CONDITIONER

12) N/A 13) N/A

C.10 Rechallenge

:2) N/A

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

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) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
  2) hair loss (Application site alopecia (10059046), Application site alopecia (10059046)
  3) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280)) (10059046))

CTU No.: FDA-CDER-CTU-2019-121551 | Department: CFSAN | RCT No.: RCT-627685 | CTU Triage Date: 20-10-2019 | Total Page

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

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		d of problem was it?	V	Were hurt or had a bad side effect (including new or worsening symptoms)				
(Check all that apply)			Used a product incorrectly which could have or led to a problem					
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			Had problems after switching from one product maker to another maker					
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Generated by: SYSTEM Generated on: 19-Oct-2019 19:45:15 Page 1 of 5

CTU No.: FDA-CDER-CTU-2019-121551 | Department: CFSAN | RCT No.: RCT-627685 | CTU Triage Date: 20-10-2019 | Total Page

Ad	dditional Comments							
				_				
100	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/Me	edicinal Food	_				
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	keratin hair straightening treatment - bran	d unknown					
	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 Generic Biosimilar	Facility					
	Strength	If Other						
	NDC number							
	Did the problem stop after the person reduced the dose or stopped taking or using the product?							
	Did the problem return if the person started taking or using the product again?							
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	5		_				
	taking or using the product							
	Date the person stopped taking or using the product							
	Give best estimate of duration							

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CTU No.: FDA-CDER-CTU-2019-121551 | Department: CFSAN | RCT No.: RCT-627685 | CTU Triage Date: 20-10-2019 | Total Page et 5

	Is therapy still on-going?				
W	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to t	reat) 1 of 1	
	cosmetic				
					ı
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device			_	
	Name of the company that makes the medical device				
Otl loc	her identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the	expiration date, if you can	
	·				
					i I
					ı
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the				
	medical device when the problem occurred?				i I
Fo	r implanted medical devices C	NI V (such as pacomako	re broast implants atc.)		
_	ate the implant was put in	NET (Such as pacemake)	Date the implant was taken or	ut (If	
	ato the implant was pat in		relevant)	ut (II	
Se	ction E - About the Person Wh	o Had the Problem			
	Person's Initials	(b) (6)			
	Gender	Female			
	Age (specify unit of time for age)	61 Year(s)			
	Date of Birth				
	Weight	71.1 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaskan Na	ative.		
		Native Hawaiian or Other Pacif			
		Asian			1
		White			ı
		Black or African American			

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

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CTU No.: FDA-CDER-CTU-2019-121551 | Department: CFSAN | RCT No.: RCT-627685 | CTU Triage Date: 20-10-2019 | Total Page e: 5

			$\overline{}$
Ple	ease list all allergies (such as t	to drugs, foods, pollen or others)	
1 10	dust mites	o drugs, 100ds, polien or others)	
	dust mites		
l is	t any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
LIC	t any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
l ic	t all current procerintian modic	cations and medical devices being used.	
LIS	t all current prescription medic	Lations and medical devices being used.	
l in	t all aver the acceptance modicati	and any vitamina minarala avinamenta and barbal remadica baira viad	
LIS	t all over-the-counter medicati	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
Se	ction F - About the Person Fill	ing Out This Form 1 of 1	
Se	ction F - About the Person Fill Primary?	ing Out This Form 1 of 1	
Se			
Se	Primary?		
Se	Primary? Reporter is Patient?		
Se	Primary? Reporter is Patient? Title	Yes	
Se	Primary? Reporter is Patient? Title Last name	Yes	
Se	Primary? Reporter is Patient? Title Last name Middle Name	Yes	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name	Yes	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	Yes	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City	Yes	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	Yes (b) (6) (b) (6)	
See	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	Yes (b) (6) (b) (6)	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code	Yes (b) (6) (b) (6)	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number	Yes (b) (6) (b) (6)	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address	Yes (b) (6) (b) (6)	
Se	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address Fax	Yes (b) (6) (b) (6)	

Generated by: SYSTEM Generated on: 19-Oct-2019 19:45:15 Page 4 of 5

CTU No.: FDA-CDER-CTU-2019-121551 | Department: CFSAN | RCT No.: RCT-627685 | CTU Triage Date: 20-10-2019 | Total Page

s: 5

Today's date	19-Oct-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 19-Oct-2019 19:45:15 Page 5 of 5

### [Close]

## **FACTS Interface**

FACTS Complaint #129433 (CAERS #163098)					
Complaint Date	11/23/2012	Complaint Source	Consumer		
Accomplishing District	DEN-DO	Complaint Status	Archived		
How Received	Telephone				

Name	(b) (6)	Work Phone	
Address	(b) (6)	Home Phone	(b) (6)
		Source POC Name	Telephone
City	(b) (6)	Source Phone	(b) (6)
State	(6) (0)		
Zip	(b) (6)		
Province			
Country	US		
Mail Code			

Adverse Event Result

Adverse Event Date

Complaint / Injur Complaint Descr	All controls and the second	
(b) (6)		two years ago she received a
"Brazilian Blowout	," which is a hair-straigh	htening treatment, at a salon.
Following the trea	ment, she experienced	a rash on her arms and
stomach. Upon se	eing her physician, he s	stated that it could be a
TO THE OWNER OF THE PARTY OF TH		om the Sun, however, the
		arms and stomach and not on
And the second s	The second secon	cortizone and sustained the
	ek. On 11/19/12(b) (6	
		ent. She went to (b) (4)
		tylist stated the product was "al
		and protein." The product is a
		ediately after receiving the
	iving home (b) (6)	stated that the "chemical
		es started burning. She stated
		. When she got home, she
		ation about the product. She
		ry "nasty" with her and would
		ingredients. The owner only

Notify EIO/EMOPS? No **Notification Date** Attended Health Professional? Yes Required Hospitalization? No Emergency Room/ No **Outpatient Visit?** Reported Complaint To? Other Need Additional/ Unknown FDA Contact? told her that it was imported from Brazil and the conversation ended. (6) (6) stated that she immediately washed the product out of her hair.

None

11/19/2012

When her eyes continued burning through Wednesday 11/21/12, she went to see a nurse practitioner at Northwest Family Medicine. She does not remember the name of the practitioner. She stated that the practitioner advised her to use eye drops when necessary. On 11/23/12, stated that her eyes no longer burn.

(b)(6)

Remarks

(b) (6) experienced moderate to severe eye burning and irritation (b) (6) reported the complaint to the Colorado Barber and Cosmetology Board. They instructed her to report her complaint to the FDA and the Boulder County Department of Health. (b) (6) that the Boulder-COH was not open on 11/23/12 when she tried contacting them. She stated that she will try to contact them again next week.

Complaint Symptoms			
Symptom Name	Duration	Remarks	
Eye irritation	2 Day(s)		

Health Care Professional						
Health Care Type	Provider Name	Address	Phone	Occupation Stay Dates		
		"		000001		

Product and Labeling						
Brand Name	Unknown	Unknown				
Product Name	Honey Brazilian Keratin	Treatment				
FDA Product Code	53EY03	Qty/Unit				
UPC Code		Package				
Exp/Use By Date		Lot/Serial				
Product Used?	Yes	Purchase Date				
Date Used?	11/19/2012	Amount Consumed/Used				
Amount Remained		Date Discontinued	11/19/2012			
Country of Origin		Imported Product?	No			
Retailer Name	Zing Hair Salon	Label Remarks				

## Manufacturer/Distributor

There is no firm information listed for this consumer complaint report.

Initial Evaluation / In	itial Disposition		
Initial Evaluation	Insuffici. Info, unable to evaluate	Initial Disposition	Closed w/o further Investigation
Disposition Date	03/06/2013		
Remarks			
Firm unknown because	se brand name of product is unknown.		
	Problem Keyword		Problem Keyword Details
Reaction		rash on her arms and	stomach

Cosmenc				
Cosmetic I	D #23801			
DOB		(b) (6)	Age	42
Gender		Female	Race	
Application	n Place	Salon/SPA	Reason for Use	Hair Preparations (Non-Coloring)
Application	n Site	Hair	Other Products?	
Directions				
Directions	Followed?		Product Duration	Day(s)
Frequency	of Use		Reaction Site	Face
Product Us	se in Off-Label Manner?		Off-Label Manner Desc	
Warning S	tatement on Label?		Warning Statements?	
Preexisting	Conditions?		Treatment	Physician
Current Sta	atus	Clear		
Medical Di	agnosis		Medical Treatment	
Eye irritatio	n/burning		OTC eye drops	
Remarks		01-11-1-1		PD
(b) (6)	was treated by a nurse practition	oner. She stated that si	ne does not remember the pro-	actitioner's name.

## Adverse Events

There is no adverse event information listed for this consumer complaint report.

[Close]

## To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 163098.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Enclosure

"Complex

1. Brand Name

AGE 12/22

U.S. Department of Health and Human Services

# MEDWATCH

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

Form Aparoved: OMB No. 0910-0291, Expires: 10/31/08 Soc OMB statement on reverse. FDA USE ONLY Trisge unit D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufasturer (from product label) Coppola Keretin Dosg or Amount Frequency 3. Dates of Use (If unknown, give duration) from/to (or bost estimate) 5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Dogsn Doosn't 42 Yas No 4. Disgnosis or Reason for Use (Indication) B. Event Reappeared After Reintroduction? HI Yes No 7. Expiration Date W2 Yas No Dosen' Apply #1 B. NDC # or Unique ID #2 E. SUSPECT MEDICAL DEVICE Coppela Keratin Complex Smoothing System 2. Common Device Name 3. Manufecturer Name, City and State LOI # 5. Operator of Davice | Health Professional Expiration Date (mm/dd/yyyy) Lay User/Patient Othor: Other # 7. If Explanted, Give Date (mm/dd/yyyy) 6. If Implanted, Give Data (mm/dd/yyyy) 8. In this a Single-use Device that was Reprocessed and Reused on a Putiant? 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) Motes 13 MR 5

The FDA Safety In		Inter	met) Submissi	on - Page
THE RESERVE THE PERSON NAMED IN	porting Program			-
A. PATIENT INFO  1. Patient Identifier (a)  1b) (0)	Age at Time of Evant, or Dale of Birth:	5. Son	4 Weight 125 To	D. SUS
AND DESCRIPTION OF THE PERSON NAMED IN COLUMN 1997 AND THE PERSON	24 Усахн	Male	orkg	12
The state of the s	VENT, PRODUCT PRO	BLEM OR ER	ROR	2. Dosg
Check all that apply:			20	+1
Product Use En	Product Problem (e.	A CARLO STORY OF THE REAL PROPERTY.		
Outcomes Attribute	Company and a series of the se	IT Manutacturer of	Same Medicine	12
(Check all that apply)				3. Dates o
Donth:	□	isability or Permane	nt Damege	best est
Z Life-threatening	(mm/dd/yyyy)	ongenital Anomaly/E	inh Defect	#1
Z Hospitalization -		ther Serious (Import		#2
	ntion to Prevent Permanent Im			4. Diagnos
3. Date of Event (mm/d		e of this Report (m		#1
03/08/201	0.77114	03/15/2013		62
Describe Event, Pro	blem or Product Use Error	to.	- Indiana	6. Let
	stylist and ha	re been us	ing the	I I I I I I I I I I I I I I I I I I I
	atin Complex Si			#1
for three y	ears. One of my	co-worke	rs gets	#2
	whenever the se			E SUS
	another gets he		nd	Сорро
burn/tear/i	my clients' ey	been hea	rina	2. Commo
mixed opini	ons when it con	nes to whe	ther or	2. Manufe
not the tre	atment is safe.	My under	standing	
is that the	product itself	does not	contain	
	e; it contains			4, Model #
able to mer	duct. The compa	as 'form	aldehvde	Catalog
free. ' Howe	ver, once it is	heated -	which it	
needs to be	in order for			Sorial #
work-, the	aldehyde	CTU	on the state	6, If Implan
		210		O. II MINDIA
	12.4			8. Is this a
	MAR	1 9 2013		Yes
			6.033	9. If Yes to
G Reinvent Tester she	eratory Data, including Dates			
, nelevant reduirease	ordery bara, melading below			
				F OTH
				Product n
			100	
			2624	
Other Relevant History	ory, including Presidenting Working and alcohol use, liverakil	edical Conditions /	e.g. allergles	0 000
THEIR ENGLISHING, SITTLE	want busy brooker must animals)	my productos, nic.)		1. Name a
				/I
				1(b)
			0	10
			(Contract)	Phone #
C. PRODUCT AV		full to STALL		2. Hoeffh F
Product Available for I	VAILA BILITY  [Valuation?   Do not send prod			Phone B (b) ( 2. Haefih P 2. You 5. If you do

G. REPORTER (See confidentiality section on back) (b) (6) 2. Haeffh Professional? 3. Occupation 4. Also Reported to: You No Other Bealth Menufacturer User Facility 5. If you do NOT want your identity disclosed Distribuler/Importer to the manufacturer, place on "X" in this box:

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

# B5. Describe event or problem continued

changes to formaldehyde, a known carcinogen. Last week I received news that a stylist in the local area who specializes in the treatment was diagnosed with lung cancer. This makes me very concerned. My questions: is the keratin treatment safe? Is it FDA regulated? Does it omit formaldehyde and if so, is it enough to be concerned about? Is it linked to cancer? Is it dangerous to just the client or stylist, or is it a potential threat to everyone in the salon?

Keratin Complex 6400 Congress Ave Suite 2000 Boca Raton, Florida 33487

To Whom It May Concern:

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If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Enclosure

U.S. Department of Health and Human Services

# MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program Internet Submission - Page 1

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

No. 0910-0291, Expires: 10/31/08 See OMB statement on reverse, FDA USE ONLY Triage unit er Use Reduced? Dogse Apply Deasn's d After Doctor's Doosn's r of Davics n Prolossional laer/Patient nddyyyy) More

A. PATIENT INFORMATION		PECT PRODUCT(S)		
The	175	Brength, Merufacturer (Irom ola Karatin	product label)	
€ remain	"Comp			
IN CONFIDENCE 24 YEARS B. ADVERSE EVENT, PRODUCT PROBLEM OR EHROR	Kg /2			
Check all that apply:	2. Dosg	or Amount	Frequency	Route
	+1			
M. Adverse Event Product Problem (e.g., detects/malfunctions) Product Use Error Problem with Different Manufacturer of Same	-		-	100
- CAMPBILL HIGH STILL MAINTEN AL SHIPE	Medicine #2			
Outcomes Attributed to Adverse Event (Check all that apply)	3 Dates o	Use(If unknown, give duratio	of frameto (as   E Euro	nt Abated After Use
☐ Death: ☐ Disability or Permanent Dam		mate)	Stop	iped or Dose Reduced?
	21	-	#1 🗆	Yes No Dogs
☐ Congenital Anamaly/Birth De		- 3		
✓ Hospitalization - initial at protonged ✓ Other Serious (Important Ma	Cichi Eveli(a)	s or Reason for Use (Indical		Yes No Dogs
Regulred Intervention to Prevent Permanent Impairment/Damage (Device	-/	a trongall to and interest	B. Ever	t Resposared After
Date of Event (mm/dd/yyy) 4. Date of this Report (mm/dd/y	2022			Yes The Door
03/08/2013 03/15/2013	62	100	100	Дряу
. Describe Event, Problem of Product Use Error	6. Lot #	7. Expiratio	n Date   42	Yas No Doose
I am a hairstylist and have been using		*1	a. NDC	For Unique (D
Coppola Keratin Complex Smoothing Trea		12		- 11-11-11-11-11-11-11-11-11-11-11-11-11
for three years. One of my co-workers		PECT MEDICAL DEVI	CE	
nosebleeds whenever the service is don	a in			
the salon, another gets headaches and coughs, and my clients' eyes often	Coppe	la Keratin Complex	Smoothing Syst	em
burn/tear/itch. I have been hearing	2. Common	Device Name		
mixed opinions when it comes to whethe		turer Name, City and Stete		
not the treatment is safe. My understan	nding	THE RESIDENCE OF THE PARTY		
is that the product itself does not con				100
formaldehyde; it contains aldehyde, a	4, Model #	Lot à		5. Operator of Davics
natural product. The company is therefable to market the product as 'formald	ehvde Catalog	# Evai	ration Date (mm/dd/yyy)	Health Prolessions
free. However, once it is heated -whi	ch it		14451 0110 (11111000),77	Lay User/Patient
needs to be in order for the product to		Othe	er 4	☐ Othor:
work-, the aldehyde	S 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			-
CIU	6, If Amples	nted, Give Data (mm/dd/yyyy)	7. If Explanted, G	Sive Date (mm/dd/yyyy)
	W 4- Miles -	Single-use Device that was	Consequent and Date	and and a Distinguish
MAR 1 9 2013	Yes		Haprocessed and Neus	60 Oil a Patignit!
William and and	P If Yes to	Item No. 8, Enter Name and	Address of Reprocess	er
	S. (OFF)		Pour Cantain	
Relevant Teste/Laboratory Data, Including Dates				
	1 74 1 1			
	F. OTH	ER (CONCOMITANT)	MEDICAL PRODU	CTS
	Product no	ames and therapy dates (no	slude treatment of event)	
	2002			
Other Relevant History, including Preexisting Medical Conditions (e.g., al	lergles.			DIGES.
mon, pregnency, smoking and alcohol use: liverificiney problems, etc.)	G. REP	ORTER (See confider	ntiality section on	back)
	1 (1994 - C. 1994 - C. 199	nd Address	4.1	
	(b) (6)			
			100	
		No. of London		The second second
C. PRODUCT AVAILABILITY		rofessional? 3. Occupation	1	4. Also Reported to:
reduct Available for Evaluation? (Do not send product to FDA)	✓ Ygp	No Other Re	alth	☐ Menutacturer
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	NOT want your identity dis	closed	User Facility
Yes No Peturned to Manufacturer on: (mm/dd/n	1 2 3 4 7 7 7	anufacturer, place on "X" in		[] Distributer/Importer

FORM FDA 3500 (8/05)

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

13MR 9

MED**W**ATCH

506132

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

# B5. Describe event or problem continued

changes to formaldehyde, a known carcinogen. Last week I received news that a stylist in the local area who specializes in the treatment was diagnosed with lung cancer. This makes me very concerned. My questions: is the keratin treatment safe? Is it FDA regulated? Does it omit formaldehyde and if so, is it enough to be concerned about? Is it linked to cancer? Is it dangerous to just the client or stylist, or is it a potential threat to everyone in the salon?

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If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Enclosure

PAGE 12/22

U.S. Department of Health and Human Services

# MEDWATCH

The FDA Safety Information Adverse Event Reporting

For VOLUNTARY reporting of adverse events, product problems and

Form Aparoved: OMB No. 0910-0291, Expires: 10/31/08 Soc OMB statement on reverse. FDA USE ONLY

FDA Safety Information verse Event Reporting Pr	and Internet   Subm	mission - Page 1	sequence #	50613	4	
PATIENT INFORMATION		D. SUSPECT	PRODUCT(S)			
etient identifier 2. Age at Time (6) Date of Birth	Female 125	1. Name, Strength	1. Name, Strength, Manufasturer (from product label) Coppola Earatin Floomplex			
In confidence 24 Ye	Male or	_kg /2				
ADVERSE EVENT, PRO	DUCT PROBLEM OR ERROR	2. Dosa or Ame	ount Frequ	eney	Route	
	ect Problem (e.g., defects/maifunctions)	+1				
	em with Different Manufacturer of Same Medic	ine to		TYCHAR -		
utcomes Attributed to Adverse I	Event					
Check all that apply)		3. Dates of Use(ff bost astimate)	unknown, givo duration) from		Abated After Use ed or Dose Reduced?	
Donth: (mm/dd/yyyy)	Disability or Permanent Damage	#1			res No Deasn't	
Life-threatening Hospitalization - initial or proton	☐ Congenital Anomaly/Birth Defect  Other Serious (Important Medical E	42			res No Descrit	
	of Permanent Impairment/Damage (Devices)		Bason for Use (Indication)		ripping	
te of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyy)	41		B. Event	Reappeared After oduction?	
03/08/2013	03/15/2013	62		#1 🗆 Y	res No Doorn't	
scribe Event, Problem of Produ	uct Use Error	6. Lot #	7. Expiration Date	W2 🗆 V	Con [ ] No [ Doesn't	
am a hairstylist	and have been using the	± #1	61	-	or Unique ID	
	mplex Smoothing Treatmen		f2	- B. 1100	or singes is	
	ne of my co-workers gets z the service is done in		MEDICAL DEVICE			
	gets headaches and	1. Brand Name				
	ents' eyes often	2. Common Device	ratin Complex Smoo	thing System	т	
rn/tear/itch.	I have been hearing		700 Land Land			
	n it comes to whether or		ame, City and State			
	is safe. My understandir t itself does not contai					
formaldehyde; it contains aldehyde, a latural product. The company is therefore able to market the product as 'formaldehyde rae.' However, once it is heated -which it		4, Model #	Lot #		5. Operator of Davice	
					Mealth Professional	
			Expiration D	late (mm/dd/yyyy)	Lay User/Patient	
	er for the product to	Sorial #	Other #		☐ Othor:	
rk-, the aldehyd	е				-	
	CIU	6. If Implanted, Gi	ve Data (mm/dd/yyyy) 7.	. If Explanted, Gh	va Date (mm/dd/yyyy)	
		8. Is this a Single	use Device that was Reproc	essed and Reuse	d on a Patient?	
	MAR 1 9 2013		No			
	F	9. If Yes to Item N	o. 8, Enter Name and Address	s of Reprocessor		
Total Charles - Barrie	- Las	02.63				
want Tests/Laboratory Dats, I	ncitioning paios					
					***	
		Description of the Party of the	ONCOMITANT) MEDIC nd therapy dates (twolude tre		15	
		F. O'G GC TIZETION N	in march during Investigating	division of Evenily		
	INC.	62.61				
or Relevant History Including		Consumary Consumer Co			METER	
pregnancy, smoking and alcoh	Presiding Madical Conditions (e.g. allergles of use, liverakings problems, etc.)	G. REPORTE	A (See confidentiality	section on L	back)	
		1. Name and Adds	( O )	2.14-27-27		
		(h)	(6)			
		(0)	(0)		,	
		Phone 8	T.	meil		
		(b) (6)		b) (6)		
RODUCT AVAILABILIT		2. Haeth Profesel		4	Also Reported to:	
Available for Evaluation7 (D	to not send product to FDA)		No Other Bealth		Menulacturer	
Yes No E Return	ed to Manufacturer on;	5. If you do NOT v	rant your identity disclosed		User Facility	

FORM FDA 3500 (8/05)

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

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

# B5. Describe event or problem continued

changes to formaldehyde, a known carcinogen. Last week I received news that a stylist in the local area who specializes in the treatment was diagnosed with lung cancer. This makes me very concerned. My questions: is the keratin treatment safe? Is it FDA regulated? Does it omit formaldehyde and if so, is it enough to be concerned about? Is it linked to cancer? Is it dangerous to just the client or stylist, or is it a potential threat to everyone in the salon?

Keratin Complex 6400 Congress Ave Suite 2000 Boca Raton, Florida 33487

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 163621.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

	oduct problems and use errors	Triage unit	M79/12
ne FDA Safety Information and diverse Event Reporting Program		sequence #	ZILIBA
PATIENT INFORMATION	D. SUSPECT PR	ODUCT(S)	PAIAA
Patient Identifier 2. Age at Time of Event, or 3. Sex 4. Weight		nufacturer ((port product (abel)	Proline
b) (6) Deta of Airth (b) (6) (6) Male of Kn	41	AN	
in confidence 66 Years L Maio	#2		
nack all that apply:	2. Dose or Amount	Frequency	Route
Adverse Event Product Problem (e.g., defects/melfunctions)	W1		
Product Uso Error Problem with Different Manufacturer of Same Modicine	#2		7 7 1,1
Outcomes Attributed to Adverse Eyent (Check all that spay)	S. Dates of Use (II unk	nown, give duration) from no (or	5. Event Abated After Use
Disability or Permanent Damage	best ostinuito) un 03/17/2012	year 04/03/2013	Stopped or Doss Reduced?
Lise-throatening Conganital Anomaly/Birth Defect		04/04/4024	Apply
Hospitalization - initial or protonged	4. Diagnosis or Rosso	n for the (Intiration)	#2 Yos No Doesn't
Required Intervention to Prevent Parminent Impoliment/Damage (Devices)		p hair conditioned	Event Responsed After     Reintroduction?
Oete of Event (mm/dd/yyyy) 9. Date of this Report (mm/dd/yyyy) 03/27/2012 04/03/2013	1/2		n1 Yes No Doesn't
Describe Event, Problem or Product Use Error	6. Lat #	7. Expiration Date	an The Doesn't
A beautician who worked at Shear Reflections	a1 26998	#1	9. NDC # or Unique ID
in Mentor, Ohio gave me a Global Keratin	#2 1365mt14	42	1365mt14
treatment. I told her I had a permanent in by hair at the time and she told me that it	E. SUSPECT ME	DICAL DEVICE	
was safe to apply the Keratin treatment over	1. Brand Name	n Straightener	
top of the permanent, She applied the treatment to the hair and then used a 450	2. Common Device Na		
legree flat iron to straighten the hair.	S. Manufacturer Name	. City and State	
For days I felt deep heat panetrations to my	Global Keratin	Corp, Ft Lauderdal	.e. Pl 33312
scalp. She told me to come back in 3 days to have it rinsed out and blow dried. The	4. Model #	Lote	5. Operator of Device
first time she did my hair, it was beautiful		26998	Health Professional
with lots of body and shine, but when I went	Catalog #	Expiration Date (n	
back for the rinse out, the hair was completely damaged in other words it was	Seriol #	Other #	Othor:
fried		7 70 6 1-00	
CTU	6. If Implented, Give D	T, II Ex	planted, Give Date (mnv/dd/yyyy)
		Dovice that was Reprocessed	and Roused on a Patient?
APR - 4 2013	Yes No	Enter Name and Address of F	Improcessor
More			
Relovant Yosty/Laboratory Data, Including Dates			
The Cleveland Clinic tells me that the hair			
will eventually grow back, but I don't believe it. My hair is so badly damaged.			
The product used is formaldehyde and the	Street, or other Persons and Publishers and Publish	COMITANT) MEDICAL	The same of the sa
doctor get hesitant when she heard this chemical was used.	Product names and th	rerapy dates (exclude treaumon	t of event)
More			
Other Relevant History, Including Pressioting Medical Conditions (a.g., silergies, risce, pregramsy, ampking and alconol use, evaluation problems, stc.)			More
	G. REPORTER  1. Name and Address	(See confidentiality sec	tion on back)
I don't smoke or drink.	/ L \ /	21	
	(D) (	0)	
	1, 1		
Kore	Phone # 4409981063	E-mail blac	kwell33windstrenm.net
. PRODUCT AVAILABILITY	2. Health Professional	7 3. Occupation	4. Also Reported to:
educt Available for Evaluation? (Do not send product to FDA)	Yes V No		Manufacturor User Facility
Y Yas   No   Hailumod to Manufacturer on: (mavod/yyyy)		your identity disclosed , place an "X" in this box:	Distributor/Importer

For VOLUNTARY reporting of

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

84/84/51 QQQQ33S01 X8

# **MEDVV**ATCH

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

#### B5. Describe event or problem continued

with no life whatscover. I began having terrible headaches and the hair began falling out. I went back to the owner, Caroline, three times and each time she told me that my hair would be okay. She said after 3 to 6 months, the keratin would be out of the hair. In the meantime I went completely bald in the top of my head - from ear to ear. I contacted the company that made the product and they claimed that she put too much heat on my head. I went to other beauty shops for treatments but nothing worked for the damage done to my hair. My last resort was the Cleveland Clinic. They have reports of many women having damage from using these products and in all cases hair loss is the major issue. I have been wearing wigs for one year because of the damage to my head. I feel a class action lawsuit needs to done in this situation.

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

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

Global Keratin Corp 5555 Ravenswood Road 16b Fort Lauderdale, Florida 33312

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 164177.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

U.S. Dupartment of Health and Human Sorvices

For VOLUNTARY reporting of

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adverse events, product problems and Triage unit product use errors The FDA Safety Information and Submission - Fage 1 495 Interne Adverse Event Reporting Program A. PATIENT INFORMATION D. SUSPECT PRODUCT(S) 2. Ago at Time of Event, or Date of Birth: Weight 116 Name, Strongth, Manufacturer (from propositional) No iltiques Formula 6 b Z Familia in Male B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR #2 Dose or Amount Frequency Chuck all that apply Route Adverse Event #1 one coat per day Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine 2. Outcomes Attributed to Adverse Event (Chack ell that apply) 3. Dates of Use(If unknown, give duration; from/to (or Event Abated After Use once per day 04/20/2013 Douth: Disability of Permanent Demage Stopped or Dose Reduced? (mm/dd/yyyy) N1 94/15/2013 #1 Yes No Doosn't Life-throutening Congonital Anomaly/binn Delect 1 lospitalization - mittal or prolonged Other Serious (Important Medical Events) Poesn Apply #2 Yes No 4. Diagnosis or Reuson for Use (Indication) nail hardener for thin nails Required Intervention to Provent Permanent Impairment/Damage (Devices) 8. Event Responsed Alter 2. Date of Event (min/dd/yyyy) Beintroduction? 4. Date of this Report (mm/dd/yyyy) Doesn't 04/20/2013 #1 Yos No 04/20/2013 5. Describe Event, Problem or Product Use Error 6. Lot # 7. Expiration Date Dossn't #2 Yes No I used Nailtiques Formula 2 Nail Hardener 9. NDC 4 or Unlaus ID and experiences a severe reaction. My fingernails were in so much pain and the nail traveled up my fingers. I believe the E. SUSPECT MEDICAL DEVICE product contained an higher level of I. Brand Name Nailtiques formaldehyde than it should have. I have 2. Common Device Name never had any reaction to any nail product in my life and I have probably used hundred 3. Manufacturer Name, City and State of different polishes and acrylic nail APR 2 2 2013 Nailtiques Mismi, FL products. This cannot be normal. I did not see anything on how to relieve this problem 4. Model # 5. Operator of Devise on any website Health Prolessions Catalog # Expiration Date (mm/dd/yyyy) Lay Usar/Pation! Oliver: Sarial # 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explented, Give Date (mm/ad/yyyy) 8. Is this a Single-use Device that was Approcessed and Reused on a Patient? 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor More 5. Relevant Yests/Leboratory Date, Including Dates F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) More More 7 Other Relevant History, including Prevainting Medical Conditions (e.g., allergian, risc, pregnancy, amoking and siconal use, lived/datay problems, etc.) G. REPORTER (See confidentiality section on back) No allergies. (b) (6) More 2. Health Professionel? 3. Occupation 4. Also Reported to: C. PRODUCT AVAILABILITY Ves V No Consumer/Non-Realth Product Available for Evaluation? (Do not send product to FDA) Munufacione

FORM FDA 3500 (8/05)

Yes No Returned to Manufacturer on:

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

if you do NOT want your identity disclosed

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

13AP &

(mm/dd/yyyy)

User Facility

Distributor/Imponar

Nailtiques 10315 102nd Terrace Sebastian, Florida 32958-7823

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

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To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 164818.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

The FDA Safety Information and

**MEDWATCH** 

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

Doesn't

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5. Operator of Device Health Professional Lay User/Patient Other:

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

Page

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	FDA USE ONLY	
Friage unit		

Adverse Event Reporting F A. PATIENT INFORMATIO			or			
1. Patient Identifier   2. Age at Tim		4. Weight	D. SUSPECT PR			
Date of Bir Sister 28 Hisp	rth	lb or	1. Name, Strength, Ma	anufacturer (from prod	luct label)	
In confidence	Male	kg	Amazon Kerati	n		
	ODUCT PROBLEM OR ERR	ROR				
Check all that apply:  1. Adverse Event Proc	1 D. 11	rsn.	2. Pose or Amount		equency	Route
	duct Problem (e.g., defects/malfunction blem with Different Manufacturer of		#2			
2. Outcomes Attributed to Adverse	The second secon	sums insureme	"-			
(Check all that apply)	2° 100 100 100 100 100 100 100 100 100 10		3. Dates of Use (If Un	known, give duration) fr	rom/to (or 5. Even	t Abated After Use
Death:(mm/dd/yyyy	Disability or Permaner	nt Damage	best estimate)	4-10-6-2		ped or Dose Reduced?
Life-threatening	Congenital Anomaly/E		#1		#1	App
Hospitalization - initial or prolo	onged Other Serious (Import ent Permanent Impairment/Damage (I	The state of the s	#2		#2	Yes □No □Doe
2.5			4. Diagnosis or Reason	on for Use (Indication)		t Reappeared After
<ol> <li>Date of Event (mm/dd/yyyy) 04/19/2013</li> </ol>	<ol> <li>Date of this Report (m 04/26/2013</li> </ol>	madryyyy)	#1			troduction?
5. Describe Event, Problem or Pro-	duct Use Error		#2	The second		App
A LEAST OF SERVING THE DIESE	a salon- Belleza Latina	e- on	6. Lot # #1	7. Expiration Do	#2 🗌	Yes □No □Doe App
THE PERSON NAMED AND PARTY OF THE	ad an allergic reaction		#2	#1	9. NDC	# or Unique ID
	along hair line. Formal			#2		
	pecific product informa er, lot number- was una	Aller Address and the Address of the	E. SUSPECT ME	EDICAL DEVICE		
manufacture and	The same of the same		1. Brand Name			
			2 Common Device No	ame		
			3. Manufacturer Name	e, City and State		
			4. Model #	Lot#		5. Operator of Devic
						Health Profession
			Catalog #	Expiration	on Date (mm/dd/yyyy	
			Serial#	Other#		Other:
		- 4				-
			6. If Implanted, Give E	Date (mm/dd/yyyy)	7. If Explanted, G	ive Date (mm/dd/yyyy)
			8. Is this a Single-use	Device that was Repr	rocessed and Reus	ed on a Patient?
			Yes No			
			9. If Yes to Item No. 8.	, Enter Name and Add	iress of Reprocesso	or
<ol><li>Relevant Tests/Laboratory Data,</li></ol>	, Including Dates	_ 4				
		3				
		- 4				
		2 1	F. OTHER (CON			CTS
		- 1	Product names and t	nerapy dates (exclude	treatment of event)	
7. Other Relevant History, Including	ng Preexisting Medical Conditions (each of use, liver/kidney problems, etc.)	e.g. allergies.	-			
, acc, pregnancy, antolong and alco	and use, inventioney problems, etc.)			(See confidentia	lity section on	back)
		7.31	1. Name and Address (b) (d)			
		- 1	147347			
		× 1	(b) (6)			
			Phone #		E-mail	
C. PRODUCT AVAILABILI	ITY		(b) (6) 9 2. Health Professions	1? 3. Occupation	1	4. Also Reported to
Product Available for Evaluation?	(Do not send product to FDA)		Yes No	A STATE OF THE STA		Manufacturer Use
Yes No Retu	rned to Manufacturer on:		5. If you do NOT want	your identity disclos	ed 🔲	Facility
Cattle of the Cattle	(m	m/dd/yyyy)	to the manufacture	r, place an "X" in this	box	Distributor/Import

Distributor/Importer

## **MED WATCH**

The FDA Safety Information and

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

Page

Form Approved: OMB No. 0910-0291, Expires:10/31/0	8
See OMB statement on revers	ε

**FDA USE ONLY** 

Triage unit sequence #

	Reporting Program		1 uge	_ •					
A. PATIENT IN				D. SUSPECT PROD	DUCT(S)				
1. Patient Identifier	2. Age at Time of Event, or Date of Birth		4. Weight	1. Name, Strength, Manuf		uct label)			
_	63 Caucasian	Female Male	kg						
In confidence	I EVENT, PRODUCT PF		OR	Mark Anthony Fr	rizz Free Ke	ratin Tre	atment		
Check all that apply:	EVENT, PRODUCT PR	COBLEM OR ERR	OK	2. Dose or Amount	Fre	equency		Route	
1. Adverse Even	.t Draduct Brablem	(a. a. dafaata(malfunatis		#1		<del>-quency</del>		toute	
Product Use E		(e.g., defects/malfunction  erent Manufacturer of S	•	#2					
	ted to Adverse Event	erent Mandiacturer or	Same Medicine	#2					
(Check all that appl									
Death:		Disability or Permaner	nt Damage	Dates of Use (If Unknown best estimate)	vn, give duration) fr		Event Abated Stopped or E		
Life-threatenin	(mm/dd/yyyy)	」 ┐Congenital Anomaly/B	irth Defect	#1			Yes		Doesn't
	ı - initial or prolonged	Other Serious (Importa		#2					─ Apply ─ Doesn't
'	vention to Prevent Permanen	] ' '	<i>*</i> I	4. Diagnosis or Reason fo	nulles (Indication)	#2	Yes	No	Apply
3. Date of Event (mm		Date of this Report (mr			or use (maication)		Event Reapp		ter
06/05/2013		06/10/2013	Tivaavyyyy)	#1		#1	Reintroduction	on? No [	□ Doesn't
5 Describe Event P	roblem or Product Use Erro	nr .				#1	res		☐ Apply
,				6. Lot#	7. Expiration Da	ite #2	Yes	No [	Doesn't Apply
	product on 06/05/	=		not available		9	NDC # or Uni	ique ID	- пррпу
	and burning skin. d received an anti				i i			.4	
	manufacturer who	-		E. SUSPECT MEDI	CAL DEVICE				
	free. She thinks t	-		1. Brand Name	CAL DEVICE				
that is releas	sed by heat. She r	eports that sh	e followed						
	nstructions. She d		ch test as	2. Common Device Name					
this was not :	indicated in the d	irections.		3. Manufacturer Name, Ci	ty and State				
				4. Model #	Lot#			erator of	
				Catalog #	Expiration	n Date (mm/dd.		Health Pro	ofessional
				Julianog #	Expiratio	II Bate (IIIII) aa.	""/ 🗆 '	Lay User/l	Patient
				Serial#	Other#		·	Other:	
				6. If Implanted, Give Date	(mm/dd/yyyy)	7. If Explante	ed, Give Date	) (mm/dd/	уууу)
				8. Is this a Single-use Dev	vice that was Penr	ocessed and F	Peused on a	Patient?	
				Yes No	vice that was Nepi	ocesseu anu r	euseu on a i	ratients	
				9. If Yes to Item No. 8, En	ter Name and Add	ress of Reprod	essor		
6 Relevant Tests/La	boratory Data, Including Da	ites.							
o. 1101014111 10010124									
				F. OTHER (CONC	•				
				Product names and there	apy dates (exclude	treatment of ev	ent)		
	story, Including Preexisting moking and alcohol use, liver/		e.g., allergies,						
				G. REPORTER (Se	e confidentia	lity section	on back)		
				1. Name and Address					
				(b) (6)					
				Phone #		E-mail			
						_ man			
C. PRODUCT A		and the SEA		2. Health Professional?	3. Occupation		4. Also	Reported	d to
Product Available fo	r Evaluation? (Do not send p	roduct to FDA)		Yes No			N	//anufactui	rer User
Yes No	Returned to Manuf		m/dd/www	5. If you do NOT want you				acility	
		(mr	m/dd/yyyy)	to the manufacturer, pl				Distributor/	Importer

PLEASE TYPE OR USE BLACK INK





July 24, 2013

Department of Health & Human Services

CFSAN / CAERS Staff (HFS-11) 5100 Paint Branch Parkway College Park, MD 20740

#### Ref: CAERS # 166420

To Whom It May Concern:

In response to your letter dated June 11, 2013 (copy attached) and the Form FDA 3500 (copy attached) the product in question is the Marc Anthony Bye Bye Frizz Keratin Smoothing Treatment.

Please be advised that this product is formulated without formaldehyde or compounds that release formaldehyde and as such the irritation experienced by this consumer could not have been caused by the release of any formaldehyde from this product. This is the only complaint we have received on this product to date.

The product has been on the market since 2011 and we have not received any complaints other than the one in question today. During the development of this product our contract manufacturer, Zotos International Inc., has confirmed that no issues were noted while testing.

If you require further information regarding this case please contact us.

Regards,

Alexander Servinis, BAS, CGA

General Manager

Marc Anthony Cosmetics Inc.

Tel: 905-530-2500 ext. 231

Toll Free (CA & USA): 1-888-295-8856

Fax: 905-530-2508

Email: <u>alex@marcanthony.com</u>

113JL R



Food and Drug Administration College Park, MD 20740

June 11, 2013

Mark Anthony 190 Pippin Road Concord, Ontario Canada COPY

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 166420.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Debra G. Street

## MED WATCH

For VOLUNTARY reporting of adverse events, product problems and product escours

of\_

6 Lot#

4. Model#

Catalog #

Serial#

not available

2. Common Device Name

D. SUSPECT PRODUCT(S)

Dose or Amount

1. Name, Strength, Manufacturer (from product label)

3. Dates of Use (If Unknown, give duration) from/to (or

4. Diagnosis or Reason for Use (Indication)

E. SUSPECT MEDICAL DEVICE

3. Manufacturer Name, City and State

If implanted, Give Date (mm/dd/yyyy)

Mark Anthony Frizz Free Keratin Treatment

7. Expiration Date

Other#

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

E-mail

Frequency.

Expiration Date (mm/dd/yyyy)

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

166420

Route

5. Event Abated After Use

#1 Yes No

#2 Yes No

Reintroduction?

#1 Yes No

#2 Yes No

9. NDC # or Unique ID

7. If Explanted, Give Date (mm/dd/yyyy)

5. Operator of Device Health Professional

Lay User/Patient Other:

8. Event Reappeared After

Stopped or Dose Reduced?

Doesn't

Apply

Doesn't

Apply

Apply

	FDA USE ONLY
Triage unit sequence #	3183

The FDA Safety Information and Page Adverse Event Reporting Program A. PATIENT INFORMATION 2. Age at Time of Event, or 4. Weight tient Identifier 3 Sax Date of Birth: X Female lb of 63 Caucasian ka Male In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply

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

**Outcomes Attributed to Adverse Event** (Check all that apply)

Disability or Permanent Damage (mm/dd/yyyy) Congenital Anomaly/Birth Defect

Other Serious (Important Medical Events) Hospitalization - initial or prolonged Required Intervention to Prevent Perma ient Impairment/Damage (Devices)

3. Date of Event (mm/dd/vyvy) 4. Date of this Report (mm/dd/yyyy) 06/05/2013 06/10/2013

5. Describe Event, Problem or Product Use Error

Consumer used product on 06/05/2013 and experienced burning eyes and burning skin. She went to the ER on 06/08/2013 and received an anti-inflammatory shot. She contacted the manufacturer who said the product was formaldehyde free. She thinks that it has formaldehyde that is released by heat. She reports that she followed application instructions. She didn't do a patch test as this was not indicated in the directions.

6. Relevant Tests/Laboratory Data, Including Dates

PLEASE TYPE OR USE

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

	C.	PRODUCT	AVAILABILITY
--	----	---------	--------------

		CD 41
Product Available for Evaluation? (Do	not sena product to	-UA)

]	Yes	☐ No	Returned to Manufacturer on;

2. Health Pro	fessional?	3. (
Yes	No	

(mm/dd/yyyy)

occupation

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

Facility Distributor/Importer

FORM FDA 3500 (10/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contribute

Mark Anthony 190 Pippin Road Concord, Ontario Canada

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 166420.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours, Libra 4. Street

Debra Street Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

#### [Close]

#### **FACTS Interface**

FACTS Complaint #122631 (CAERS #	166590)		
Complaint Date	10/03/2011	Complaint Source	Consumer
Accomplishing District	FLA-DO	Complaint Status	Archived
How Received	Telephone		

Name	(b) (6)	Work Phone	
Address	(b) (6)	Home Phone	(b) (6)
		Source POC Name	
City	(b) (6)	Source Phone	
State	(6) (0)		
Zíp	(b) (6)		
Province			
Country	US		
Mail Code			

# Complaint Description Complainant stated she had her hair treated with Coppola Keratin

Complainant stated she had her hair treated with Coppola Keratin Smoothing Therapy Complex by her hairdresser. She stated she started losing her hair the next day and to date has lost 60% of her hair. She has seen a doctor who did blood tests and stated she is healthy and the hair loss is probably due to the product. She has looked on the internet and seen several other references to this problem.

**Adverse Event Result** Non-serious Injuries/ Illness **Adverse Event Date** 05/2011 Notify EIO/EMOPS? Yes **Notification Date** 10/03/2011 Attended Health Professional? Yes Required Hospitalization? No Emergency Room/ No **Outpatient Visit?** Reported Complaint To? Need Additional/ **FDA Contact?** 

#### Remarks Hair loss

Complaint Symptoms

Complaint / Injury

Complaint Symptoms					
Symptom Name	Duration	Remarks			
Balding	null null	Still losing up to 60% total hair loss so far			

Health Care Professiona	al				
Health Care Type	Provider Name	Address	Phone	Occupation	Stay Dates
(b) (4)					

Brand Name	Coppola		
Product Name	Keratin Smoothing Therapy		
FDA Product Code	53ED03	Qty/Unit	
UPC Code		Package	
Exp/Use By Date		Lot/Serial	
Product Used?	Yes	Purchase Date	
Date Used?	07/2011	Amount Consumed/Used	
Amount Remained		Date Discontinued	
Country of Origin		Imported Product?	No
Retailer Name	Tangles Hair Salon	Label Remarks Had put on by hairdresser	

#### Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3008765426	Keratonics 4377 NW 124th Ave Coral Springs FL 33065	FLA-DO	Manufacturer

Initial Evaluation / Initial Disposition						
Initial Evaluation	FDA Action Indicated	Initial Disposition	Referred to Other FDA District			
Disposition Date	10/07/2011					
Remarks						
60 % hair loss would not a	60 % hair loss would not allow NWE-DO to put in adverse events greyed out?					
Pro	blem Keyword	Pro	blem Keyword Details			
Other		60% Hair Loss				

Cosmetic			
Cosmetic ID #21399			
DOB		Age	
Gender	Female	Race	
Application Place	Salon/SPA	Reason for Use	Hair Preparations (Non-Coloring)
Application Site	Hair	Other Products?	
Directions			
Directions Followed?		Product Duration	
Frequency of Use		Reaction Site	Scalp
Product Use in Off-Label Manner?		Off-Label Manner De	esc
Warning Statement on Label?		Warning Statements	?
Preexisting Conditions?		Treatment	
Current Status			
Medical Diagnosis		Medical Treatment	
Remarks			

#### Adverse Events

There is no adverse event information listed for this consumer complaint report.

[Close]

Keratonics 4377 NW 124th Ave Coral Springs, Florida 33065

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 166590.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

U.S. Department of Health and Human Services

A. PATIENT INFORMATION

2. Outcomes Attributed to Adverse Event

Hospitalization - Initial or prolonged

5. Describe Event, Problem or Product Use Error

Relevant Tests/Laboratory Data, Including Dates

(b) (6)

Check all that apply: V Adverse Event

(Check all that apply)

Life-throwening

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

11/03/2012

Douth:

(b)(4)

wet. I

requests.

treatment.

C. PRODUCT AVAILABILITY

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

Yes No Actumed to Manufacturer on:

## **EDWATCH**

2. Age at Time of Event, o

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Required Intervention to Prevent Permanent Impairment/Dament (Devices)

On 03/Nov/2012, I decided to get a keratin

treatment after being convinced by my hair

Heavener, told me that I would "love it." After an approximately three hour process

wash my hair for three days. Within one

week of receiving the keratin treatment, my

hair began abnormally shedding excessively. Large chunks of my hair began falling out at

the root and breaking off. When I washed it,

my hair had a completely different texture

that I can only describe as "mushy" when

Blood work to be done per my doctors

Other Relevant History, including Preciating Modical Conditions (e.g., ullergies race, pregnancy, smoking and alsohol use, livertidiney problems, etc.)

No personal or family history of hair loss. No history of nosebleeds until keratin

with excessive fumes and burning, the procedure was done. I was not allowed to

(b) (6)

(mm/dd/yyyy)

product use errors The FDA Safety Information and Internet Submission - Page 1 Adverse Event Reporting Program

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

Z Fem

Mala

Dispility or Permanent Damage

Congonital Anomaly/Sinh Defect

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

06/17/2013

The owner of the salon, Mark

Other Serious (Important Medical Events)

toment on reverse.

For VOLUNTARY reporting of adverse events, product problems and Triage unit D. SUSPECT PRODUCT(S) Name, Strongth, Manufacturer (from product label) Coppola keratin "Itreatment 42 Dose or Amount Fraguency Route #2 3. Dales of Use(II unknown, give duration) from/to for 5. Event Abuted After Use Stopped or Dase Reduced? Dousn't #1 11/03/2012 11/03/2012 #1 Yes Z No #2 Yes No Apply 4. Diagnosis or Resson for Use (Indicason) 9. Event Respected After Reintroduction? 41 Yes No Doosn' #2 Yes No Douse 6. Lot # 7. Expiration Date 9. NDC & or Unique ID 12 E. SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common Device Name JUN 1 8 2013 3. Manufacturer Namo, City and State Salon Heavener, Laguna Hills, CA 4. Model # 5. Operator of Davice Hoalin Professional Expiration Date (mm/ttd/yyyy) Catalog # Z Lay User/Pations Other: Other # Serial # 7. H Explented, Glus Date (mnvddyyyy) 6. If Implanted, Givo Date (num/dd/yyyy) 6. Is this a Single-use Dovice that was Reprocessed and Roused on a Patient? 9. If Yes to Item No. 8, Enter Name and Address of Reprocuesor F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dutes (exclude treatment of event) None. 13.JN 5 More G. REPORTER (See confidentiality section on back) E-mail elenavelsh@hotmail.com 2. Health Professional? 3. Occupation 4. Also Reported to: Manufacturer Consumer / Non-Health Yes V No User Facility

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

Distributor/Importer

More

More!

More

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

515388

# MED**VV**ATCH

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

#### B5. Describe event or problem continued

continued losing excessive amounts of hair on a daily basis from the root. Within two weeks of receiving the keratin treatment, a bald spot on the top of my head appeared about the size of a quarter. The area was completely bald. Over the course of the next several months, my hair continued to fall out in chunks. The bald spot increased in size to about the size of my palm. During this time, I also developed nose bleeds which now come every two weeks. After seeing doctors, I was diagnosed with alopecia areata and have to receive cortisone injections on my head to hopefully stop the hair loss. This is quite traumatizing for someone who has had thick, long hair her entire life. I have never experienced hair loss and have not had nosebleeds until I received this keratin treatment. I believe the product used by this salon is toxic and should not have been used. The salon did not inform me of side effects and did not make me wear a mask while the procedure was being done. I am so traumatized over my loss of hair and bald spots. Seven months post-keratin treatment, my once thick mane has thinned out significantly and I continue to lose massive amounts of hair by the root daily and there is no Either the ingredients in the product caused me to lose my hair or the end in site. procedure was clearly done improperly.

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

Consumer Report

16951

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011

FDA USE ONLY

## U.S. Department of Hearth and Human Services MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

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

Page tof2

nage unit C75AN Dose or Amount Frequency 211 #2 3. Dates of Use (If unknown, give duration) from/to 5. Event Abated After Use Stopped or Dose Reduced? #1 08/15/2013 -#1 Yes No Doesn't #2 Yes No Doesn't 4. Diagnosis of Reason for Use (Indication) 5. Event Reappeared After Reintroduction? #1 Salon treatment to smooth bair #1 Yes No Doesn'i Apply #2 Yes No Doesn't 6. Lot# 7. Expiration Date 9. NDC # or Unique ID #2 E. SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common Device Name CIU 406 2 7 2013 3. Manufacturer Name, City and State 5. Operator of Device 4. Model & Lot # Health Professional Catalog # Expiration Date (mrn/dd/yyyy) Lay User/Patient Other: Serial # Other # 6. If Implented, Give Date (mn/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor F. OTHER (CONCOMITANT) MEDICAL PRODUCTS roduct names and therapy dates (exclude treatment of event) G. REPORTER (See confidentiality section on back) Name and Address Name: (b) (6) 13 AU % Address: chy. (b) (6) Statu: (0) (6 21P: (b) (6) Phone # E-mall (b) (6) (b) (6) 4. Also Reported to: 2. Health Professional? 3. Occupation Manufacturer

 Patient Identifier 2. Age at Time of Event or Date of Birth: 104 lb V Famale 42 YEATS (b) (6) Male in confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR 1 Adverse Event Product Problem (e.g., defects/multunctions) Product Use Error Problem with Different Manufacturer of Same Medicine 2. Outcomes Attributed to Adverse Event (Chack all that apply) Death: Disability or Permanent Damage (mm/dd/yyyy) Life-threatening Congunital Anomaly/Gifth Defect ☐ Holipitalization - initial or prolonged ☑ Other Serious (Important Madical Svenis) Required Intervention to Prevent Permanent Impairment/Damane (Devices) 3. Date of Event (mm/dd/yyyy) 4 Date of this Report (mm/dd/yyyy) 08/15/2013 00/26/2013 5. Describe Event, Problem or Product Use Error Went to Salon Ziba in Manhattan (NYC) on Thursday, 8/15/13 for Brazilian Keratin Treatment (Brazilian Blowout! . Margerita placed solution directly on my scalp as if shampooing in my hair and scalp. I don't think the solution should have been placed directly on my scalp. The solution was never rigged from my hair/ scalp and I was instructed by Margerita to not wash it until the next day. During the treatment, I told Margerito that my scalp was burning. The next day, my scalp, eyes, nose and throat were burning and I was having sifficulty breathing. I washed it out once I woke up. 6. Relevant Tests/Laboratory Data, Including Dates. Went to doctor on Monday, 8/19/13 complaining of back pain near kidneys, nausea, burning scalp, eyes, nose, throat, and hair loss since Brazilian koratin treatment on 8/15/13. My doctor ran blood test. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liverhidney problems, etc.) Race: White Medical Conditions: n/a Allergies: nuts, pollen Important Information: n/a RX Meds: n/a OTC Mods: n/a C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufecturer (from product label) #1 Name: Brazilian kératin treatment Strength: Manufacturer beazilien blowout Yes No #2 Name: User Facility 5. If you do NOT want your identity disclosed Strength: Distributor/Importer to the manufacturer, place an "X" in this box: Manufacturer: Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

000001

FORM FDA 3500 (1/09)

#### [Close]

#### **FACTS Interface**

FACTS Complaint #130790 (CAERS #169965)					
Complaint Date	02/19/2013	Complaint Source	Consumer		
Accomplishing District	NWJ-DO	Complaint Status	Archived		
How Received	Email				

Name	(b) (6)	Work Phone	
Address	(b) (6)	Home Phone	(b) (6)
0.000000		Source POC Name	
City	(b) (6)	Source Phone	
State	(p) (0)		
Zip	(b) (6)		
Province			
Country	US		
Mail Code			

# Complaint / Injury Complaint Description Consumer alleged she experienced an allergic reaction after using Suave Keratin Infusion Conditioner on 2/13. Within a day she developed hives all over her body. Reaction began on her scalp which was red, bumpy and itchy. It moved to the back of her neck, down her torso and to her legs. She saw a doctor on 2/14 and been on a tapered dose of Prednisone along with antihistamines. By 2/19 her condition has improved. Other product used for haircare is John Frieda shampoo. She's 60 yrs old, born 12/3/1952. She threw remaining product away and does not have any product codes. Product was purchased the week of Feb 4th, 2013 from CVS.

Adverse Event Result	None
Adverse Event Date	2/14/2013
Notify EIO/EMOPS?	Yes
Notification Date	02/19/2013
Attended Health Professional?	Yes
Required Hospitalization?	No
Emergency Room/ Outpatient Visit?	No
Reported Complaint To?	Unknown
Need Additional/ FDA Contact?	No

#### Remarks

No product is remaining

Complaint Symptoms				
Symptom Name	Duration	Remarks		
Hives (urticaria, welts)	5 Day(s)	Hives all over body		
Itching	5 Day(s)	scalp		

Health Care Professional					
Health Care Type	Provider Name	Address	Phone	Occupation Stay Dates	
(b) (4)	(b) (4)	(b) (4)	(b) (4)		

Product and Labeling					
Brand Name	and Name Suave				
Product Name	Keratin Infusion Co	nditioner			
FDA Product Code	53ED03	Qty/Unit			
UPC Code	not available	Package	Bottle		
Exp/Use By Date	not available	Lot/Serial	not available		
Product Used?	Yes	Purchase Date	02/2014		
Date Used?	02/13/2013	Amount Consumed/Used	1 bottle		
Amount Remained	none	Date Discontinued	02/13/2013		
Country of Origin		Imported Product?	No		
Retailer Name	cvs	Label Remarks Unilever			

#### Manufacturer/Distributor

FEI Name & Address Home District Firm Type

3004778869 Unilever United States, Inc. 800 Sylvan Ave Englewood Cliffs NJ 07632-3113 NWJ-DO Corporate Headquarters

#### Initial Evaluation / Initial Disposition

Initial Evaluation FDA Action Indicated Initial Disposition Referred to Other FDA District

Disposition Date 09/13/2013

Remarks

NWE-DO contacted Unilever and spoke with Lauren Mulroy to identify the manuf. 201-227-5921. She said without the lot or UPC she can not determine the location of the plant. CC was referred to NWJ-DO as FYI.

Problem Keyword Details

Allergic Reaction itching, redness, hives

Cosmetic				
Cosmetic ID (b) (6)	The same of the sa			
DOB	(b) (6)	Age	60	
Gender	Female	Race	Unknown	
Application Place	Home	Reason for Use	Hair Preparations (Non-Coloring)	
Application Site	Hair	Other Products?	Yes	
Directions				
Yes				
Directions Followed?	Yes	Product Duration	Day(s)	
Frequency of Use	Other	Reaction Site	Scalp	
Product Use in Off-Label Manner? No		Off-Label Manner Desc		
Warning Statement on Label?		Warning Statements	?	
Preexisting Conditions?		Treatment	Physician	
Current Status	Improved			
Medical Diagnosis		Medical Treatment		
Remarks				

#### Adverse Events

Used once

There is no adverse event information listed for this consumer complaint report.

[Close]

Unilever United States, Inc. 920 Sylvan Ave. Englewood Cliffs, New Jersey 07632-3313

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 169965.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Consumer Report

Form Approved: OMB No. 0910-0281, Expires: 12/31/2011 See OMB statement on reverse.

## U.S. Department of Health and Human Services MEDWATCH

Adverse Event Reporting Program

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

FOA USE ONLY Triage unit 504010 The FDA Safety Information and Page + of 2 A. PATIENT INFORMATION Dose or Amount Frequency Route Date of Birth: (b) (6) 150 b 7 Female 51 Years #2 (b) (6) Male Male in confidence Dates of Use (If unknown, give duration) from/to (or basil estimate) B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR 5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doasn't #1 1. Adverse Event Product Problem (e.g., defects/mail/unctions) #2 Product Use Error Problem with Different Manufacturer of Same Medicine #2 Yes No Desent 4. Diagnosis or Reason for Use (Indication) 2. Outcomes Attributed to Adverse Event (Check ull that apply) 8. Event Reappeared After Reintroduction? Death: Disability or Parmanent Damage #1 Yes No Doesn't (mm/dd/yyyy) 72 Life-threatening Congenital Anomaly/Birth Defect #2 Yes No Doesn't ☐ Hospitalization - Initial or prolonged ☐ Other Serious (Important Medical Events) 7. Expiration Date 6. Lot # Required Intervention to Prevent Permanent Impairment/Damage (Devices) 9. NDC # or Unique ID #2 #2 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) E. SUSPECT MEDICAL DEVICE 09/13/2013 09/14/2013 Brand Name 5. Describe Event, Problem or Product Use Error I had the Brazilian Blow Out treatment done on my hair yesterday. I had breathing problems and my eyes hurt that much that I was in toars, I didn't sleep last 2. Common Device Name night because I have a terrible headsche and my eyes are very irritated. I fael very sick. 3. Manufacturer Name, City and State 4. Mudel # Lot # 5. Operator of Device Health Professional Expiration Date (rnm/dd/yyyy) Lay User/Patient Catalog # Other: 6. Relevant Tests/Laboratory Deta, including Dates Serial # Other B 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/bd/vvvv) CIU 6. Is this a Single-use Device that was Reprocessed and Reused on a Patient? YBB No SEP 1 6 2013 9. If Yos to Ham No. 5, Enter Name and Address of Reprocessor Other Relavant History, including Preaxisting Medical Conditions (s.g., allergies, race, pregnancy, smoking and alcohol use, liverhidney problems, etc.) Raco: -- Medical Conditions: none Allergies: none F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Important Information: none RX Meds: none OTC Mess: reduct names and therapy dates (exclude treatment of event) vitamin D G. REPORTER (See confidentiality section on back) Name and Address C. PRODUCT AVAILABILITY Name: (b) (6) Freduct Available for Evaluation? (Do not sand product to FDA) Address: (b) (6) Yes No Returned to Menufacturer on: mm/dd/yyyy) city: (b) (6) \$tate: FI ZIP (b) (6) D. SUSPECT PRODUCT(S) Phone # E-mail Name, Strength, Manufacturer (from product label) (b) (6) (b) (6) #1 Name brozilian blow out Strength: 4. Also Reported to: 2. Health Professional? 3. Occupation

FORM FDA 3500 (1/09)

Manufacturer: braziliam blow out

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

5. If you do NOT want your identity disclosed

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

Yes No

Distributor/Importer

#2 Name:

Strength:

Manufacturer"

TYPE OR USE BLACK INK

EASE

E

Manufacturer

User Facility

Brazilian Blowout 6855 Tujunga Ave North Hollywood, California 91605-6312

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 170162.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

U.S Department of Health and Human Services

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

7 Female

Male

Disability or Permanent Damage

Congenital Anomaly/Birth Defect

09/17/2013

4. Date of this Report (min/dc/yyyy)

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

Mospitalization - Initial or prolonged ☑ Other Serious (Important Medical Events)
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)

July, 2010 Female age 45 - Salon used Prayana smoothing treatment (Kerstin Treatment). I was told not to wash my hair for 3 days. After my first hairwash my shower drain was filled with an alarming amount of hair and my scalp, neck and body were itching for months. My hair has continued to fall out (from the root), and is presently still shedding 3 years later. Initially a lot of the hair strands that fell out were thin and looked simost clear. I have lost about 1/2 the hair on my scalp and doctors say it

could be from the keratin treatment (which was supposedly formaldahyde free) but they ...

170285

Farm Approved: OMB No. 0910-0291, Expres: 12/31/2011

## MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

 Outcomes Attributed to Adverse Event (Check all that apply)

5. Describe Event, Problem or Product Use Error

6. Relevant Tests/Laboratory Data, Including Dates

(b) (6)

A. PATIENT INFORMATION

1. Patient identifier 2. Age at Time of Event or
(b)(b)

Date of Birth:

in confidence

Check all that apply:

Death:

Life-threatening

07/23/2010

TYPE OR USE

EASE

2

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

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

Page 1 of 2

KO

cr problems and	Triage unit	A USE ONLY
of 2 E75A	W- WALLENDAR # TA	24617
2. Dose or Amount #1	Fraquency	Route
3. Dates of Use (If uni (or best estimate)	known, give duration) fromvto	S. Event Abated After Use Stopped or Doss Reduced? #1 Yes No Dossn't Apply
	on for Use (Indication)	#2 Yes No Doesn't
	stment to smooth	8 Event Reappoared After Reintroduction? #1 Yes No Doesn't Apply
6. Lot #	7. Expiration Date	#Z Yes No Doesn't
#2	#2	9. NDC # or Unique ID
	EDICAL DEVICE	
1. Brand Name		CTU
2. Common Device N	ame	SEP 1 8 2013
S. Manufacturer Name	e, City and State	
4 Model #	Lot#	5 Operator of Device
Catalog #	Expiration Date (m)	middlyyyy) Lay User/Patient
Serial #	Other #	L. Odiel.

7. Other Relevant History, including Preaxisting Medical Conditions (e.g., alternes, race, pregnancy, smoking and atcohol use, Eventidiney problems, etc.)
Race:-- Medical Conditions: Flevated cholesterol level
Allergies: pollen, ragueed, cats Important
Information: Healthy, active, never lost/shud hair
before July or 2010 RX Meds: storoid foam was used OTC

Slood Tests from 2010 to present checking for thyroid inques, hormone levels, and other deficiencies.

Meda: viviscal, daily multivitimins, biotin, iron supplements were all used

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

9. If Yes to flam No. 8, Enter Name and Address of Reprocessor

8. Is this a Single-use Davice that was Reprocessed and Roused on a Patient?

6. If Implanted, Give Date (mm/dd/yyy/)

Yes No

Name and Address

Address:

City:

Phone #

(b)(6)

Name: cathy dipenta

### C. PRODUCT AVAILABILITY

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

Yes Z	No 🗆	Returned to	Manufacturer	on:
-------	------	-------------	--------------	-----

#### D. SUSPECT PRODUCT(S)

4. Name, Strength, Manufacturer (from product label)

Mame: Pravana Smoothing System Strength:

Manufacturer

#2 Name: Strength: Manufacturer

FORM FDA 3500 (1/09)

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

Yes No

2. Health Professional? 3. Occupation

5. If you do NOT want your identity disclosed

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

Distributor/Importer

133P#

000001

(mm/dd/yyyy)

4. Also Reported to:

Manufacturer

User Facility

7. If Explanted, Give Date (mm/dd/yyyy)

State: -- ZIP:

E-mail

(b)(6)

## 524617

## **MEDWATCH**

The FOA Safety Information and Adverse Event Reporting Program

# (CONTINUATION PAGE) For VOLUNTARY reporting of adverse events and product problems

Page 2 of 2

As Describe Event of Problems (continued).  . Can't know for suck. I have had many blood tegts for posable causes and nothing comes up. THE NATIONS STRATED APTER THE KERATHIN TREATHENT. I NEVER HAD IT BEFORE THE TREATMENT. SOMETHING REPERCED TO MY HARR HATE THE CREATMENT AND THE USE. The salon said nobody else has complained. That would they teal me if they had? I have had some regrowth but that hair as very fine and also fails out. IT STRATED INTEGRATED ATTEMPTS AND THE STRATE AND THE REPORT OF THE KERATHIN THE KERATHIN THE KERATHING THE STRATE AND THE S		
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F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)		- 1
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Pravana Naturceuticals . 23285 Ventura Blvd Woodland Hills, California 91364

To Whom It May Concern:

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If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

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

I1390487A

## **NEDWATCH**

The FDA Safety Information and Adverse Event Reporting Program

PLEASE TYPE OR USE BLACK INK

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

Page	of	
aye	 v.	

See OMB statement on reverse. FDA USE ONLY

Triage unit

170362 A. PATIENT INFORMATION D. SUSPECT PRODUCT(S) 1. Patient Identifier 2. Age at Time of Event, or 3. Sex 4. Weight 1. Name, Strength, Manufacturer (from product label) Date of Birth: Female Brazillian Blowout (Original) Hair Male Straightening B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Route Dose or Amount Frequency Check all that apply: #1 1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine #2 2. Outcomes Attributed to Adverse Event (Check all that apply) 5. Event Abated After Use 3. Dates of Use (If unknown, give duration) from/to (or Stopped or Dose Reduced? Disability or Permanent Damage Death: #1 Yes No Doesn't (mm/dd/yyyy) Congenital Anomaly/Birth Defect Life-threatening Doesn's Other Serious (Important Medical Events) #2 Yes No Hospitalization - initial or prolonged 4. Diagnosis or Reason for Use (Indication) Required Intervention to Prevent Permanent Impairment/Damage (Devices) 8. Event Reappeared After Reintroduction? 4. Date of this Report (mm/dd/yyyy) 3. Date of Event (mm/dd/yyyy) Doesn' Apply #1 Yes No 03/25/2013 09/23/2013 #2 Doesn't Apply 5. Describe Event, Problem or Product Use Error 6. Lot # 7. Expiration Date #2 Yes No 9. NDC # or Unique ID #2 See attached: E. SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common Device Name 3. Manufacturer Name, City and State 4. Model # 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Other: Serial # 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 6. Relevant Tests/Laboratory Data, Including Dates F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, G. REPORTER (See confidentiality section on back) race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) 1. Name and Address (b) (6) Phone # 2. Health Professional? 3. Occupation 4. Also Reported to: C. PRODUCT AVAILABILITY Yes No Manufacturer Product Available for Evaluation? (Do not send product to FDA) User Facility 5. If you do NOT want your identity disclosed Yes No Returned to Manufacturer on: Distributor/Importer to the manufacturer, place an "X" in this box: (mm/dd/yyyy)

This is a copy of your Report to the U.S. Consumer Product Safety Commission submitted on 9/23/2013

#### Incident Details

Document |1390487A

Number:

Report Number: 20130923-98F41-2147451605

Report 9/23/2013

Submitted

Date:

Who You Are: Consumer

Incident I had a certified salon professional use the Brazilian Blowout (Original) hair straightening Description: treatment on my hair. Immediately following this treatment, my hair began falling out. At first, I thought it was only shedding due to the harsh chemicals and it would be temporary. However, it continued. It has not stopped "shedding" since April and I have now lost almost half of my hair. Other people have noticed and began telling me, including my salon professional who has been cutting my hair for years.

> I have just ordered hair vitamins and plan to see my dermatologist as well. My hair has never fallen out before and I've always had very thick, curly, shiny and healthy hair. It is now damaged and I find clumps of hair in my shower and my brush and any time I touch my hair several strands just fall out. It is far beyond any norm in my 44 years.

I'm extremely concerned about this product and I know the salon professional used all of the guidelines to administer it properly.

Incident Date: 3/25/2013

Incident Home/Apartment/Condominium - P.O. Box 5015, Santa Monica, California, 90409, United States

Location:

#### Victim Details

First Name: (b) (6)

Last Name: (b) (6)

Injury Incident, No Injury

Information:

Victim is of No

Hispanic/Latino

origin?

Race: White

Other

Race/Ethnicity:

My Relationship Self

to Victim:

Gender: Female

Age when 44 Years

incident occurred:

Address: (b) (6)

E-mail: (b) (6)

Phone Number: (b) (6)

#### **Product Details**

Product Brazilian Blowout Acai Professional Soothing Solution (Original) Brazilian Blowout Acai Anti-Frizz Description: Shampoo & Conditioner Brazilian Blowout Acai Daily Smoothing Serum Brazilian Blowout Acai Protective Thermal Straightening Balm

CPSC does not guarantee the accuracy, completeness, or adequacy of the contents of the Publicly Available Consumer Product Safety Information Database on SaferProducts.gov, particularly with respect to information submitted by people outside of CPSC.

Product Personal Care

Category:

Product Type: Grooming

Brand Name: Brazilian Blowout

Manufacturer / BrazilianBlowout.com

Importer /

Private Labeler

Name:

Model Name or

Number:

Serial Number:

Date

Manufactured:

Manufacturer

Date Code:

Manufacturer Not specified

Address:

Manufacturer

Website URL:

Manufacturer

Phone Number:

Retailer:

Retailer State:

#### Additional Details

Purchase Date:

I still have the Yes

product in my

possession.

The product No

was damaged

before the

incident.

The product No

was modified

before the

incident.

Have you Yes

contacted the

manufacturer?

If not, do you N/A

plan to contact

them?

Explanation: I contacted the mfg today for an Material Safety Data Sheet to bring to my dermatologist.

Your Contact Information

First Name: Marie

Last Name: Roviello

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Address: P.O. Box 5015, Santa Monica, California, 90409, United States

E-mail (b) (6)

Phone Number: (b) (6)

#### Consent

May we include Yes, you may include my Report with any attachments on SaferProducts.gov.

your Report,

including any

documents or

photographs

that you have

attached to

your Report,

but without

your name and

contact

information, in

CPSC's Public Database?

May we release Yes, you may release my name and contact information to the product manufacturer / importer / your name and private labeler.

contact

information to

the product

manufacturer /

importer /

private labeler

identified in

your Report?

I certify that I Yes

have reviewed

the Report and

that the

information

provided in this

Report is true and accurate to

the best of my

knowledge, information,

and belief.

OMB Control Number(b) (6)

CPSC does not guarantee the accuracy, completeness, or adequacy of the contents of the Publicly Available Consumer Product Safety Information Database on SaferProducts.gov, particularly with respect to information submitted by people outside of CPSC.

Brazilian Blowout 28001 Dorothy Dr Agoura Hills, California 91301-2609

To Whom It May Concern:

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If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition



## DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

CFSAN

Form Approved: OMB No. 0910-029
Expiration Date: 6/30/201
(See PRA Statement on preceding general information page)

# MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

Section A	About the Problem 172434
What kind of problem was it? (Check all that apply)	Did any of the following happen? (Check all that apply)
<ul> <li>Were hurt or had a bad side effect (including new or worsening symptoms)</li> <li>Used a product incorrectly which could have or led to a problem</li> <li>Noticed a problem with the quality of the product</li> <li>Had problems after switching from one product maker to another maker</li> </ul>	<ul> <li>☐ Hospitalization – admitted or stayed longer</li> <li>☐ Required help to prevent permanent harm (for medical devices only)</li> <li>☐ Disability or health problem</li> <li>☐ Birth defect</li> <li>☐ Life-threatening</li> <li>☐ Death (Include date):</li> <li>☐ Other serious/important medical incident (Please describe beloen)</li> </ul>
Date the problem occurred (mm/dd/yyyy)	
May 2013 - August 2013	
Tell us what happened and how it happened. (Include as many of My hair dresser gave me a product to use in my hair to help wit distributor told her this and used it as a selling point. I used the then it became stiff at the roots and started to fall out in hand for	th straightening. She said it was an all natural raw keratin protein. The product for a month. My hair began to present very oily.
	yroid panel with TSH, Iron and TIBC, Vit B12 and folate, FSH and Rheumatoid Factor, Vit D, Hydroxy, C-reactive protein, Cardiac,
Problem with a product, including     prescription or over-the-counter medicine     biologics, such as human cells and tissues used for trans (for example, tendons, ligaments, and bone) and gene th     nutrition products, such as vitamins and minerals, herbal formulas, and medical foods     cosmetics or make-up products     foods (including beverages and ingredients added to food	remedies, infant
For a problem with a medical device, including  any health-related test, tool, or piece of equipment  health-related kits, such as glucose monitoring kits or blo  implants, such as breast implants, pacemakers, or cathel  other consumer health products, such as contact lenses, breast pumps	ters (Skip Section B)

FORM FDA 3500B (4/13)

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

**MedWatch** Consumer Voluntary Reporting

Page 1 c

Submission of a report does not constitute an admission that medical

personnel or the product caused or contributed to the event.

		Section B	- About the Products		
Name of the product as it app			age (Include as many name	es as you s <del>ee</del> )	
Raw native keratin, Mane Ta					
Name of the company that m Unknown - Distributed by Da			ngress ave, suite 503, Delra	ry Beach, FL 33445. 877-243-7980	
Expiration date (mm/dd/yyyy) NA		Lot number NA		NDC number NA	
Strength (for example, 250 mg per 500 mL or 1 g)		(for example, 2 pills, or 1 teaspoon, etc.)	Frequency (for example, twice daily or at bedtime, 1-3 times per week		
Date the person first started to or using the product (mm/dd/	(yyyy): 05/1	4/2013	supposed to treat?)	ng the product (such as, what condition was i	
Date the person stopped taking the product (mm/dd/yyy		14/2013	Help moisturize and stra	ighten hair.	
Did the problem stop after the person reduced the dose or staking or using the product?		☐ Yes ⊠ No			
Did the problem return if the pathe product again?	person sta	ted taking or using		uct in case we need to evaluate it? (Do not We will contact you directly if we need it.)	
Yes I	Vo ⊠ I	Didn't restart	⊠ Yes □ No		
☐ Go to Section D	(Skip Sec	tion C)			
		Section C - A	bout the Medical Devic		
Name of medical device  Name of the company that me	akes the m	***************************************	bout the Medical Devic		
Name of the company that me		nedical device		iration date, if you can locate them)	
Name of the company that me		nedical device			
Name of the company that ma Other identifying information (	The mode	nedical device			
Name of the company that ma	The mode	nedical device I, catalog, lot, serial, o	or UDI number, and the exp		
Name of the company that man of the identifying information (	If yes, w	nedical device  I, catalog, lot, serial, of the was using it? The person who had the nealth professional (se	problem  uch as a doctor, nurse, or a	iration date, if you can locate them)	
Name of the company that me Other identifying information (  Was someone operating the medical device when the problem occurred?	If yes, w	nedical device  I, catalog, lot, serial, of the was using it? The person who had the	problem  uch as a doctor, nurse, or a	iration date, if you can locate them)	
Name of the company that ma Other identifying information (  Was someone operating the medical device when the problem occurred?  Yes  No	If yes, w	nedical device  I, catalog, lot, serial, of the was using it? The person who had the the mealth professional (so	problem uch as a doctor, nurse, or a	iration date, if you can locate them)	
Name of the company that me Other identifying information (  Was someone operating the medical device when the problem occurred?	If yes, wi	nedical device  I, catalog, lot, serial, of the person who had the the person who had the the person else (Please el	problem uch as a doctor, nurse, or a explain who)	iration date, if you can locate them)	
Name of the company that me Other identifying information (  Was someone operating the medical device when the problem occurred?  Yes  No	If yes, wi	nedical device  I, catalog, lot, serial, of the person who had the the person who had the the person else (Please el	problem uch as a doctor, nurse, or a explain who)	iration date, if you can locate them) ide)	

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

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

1		ion D - About the Per	CALL CONTROL OF CASE O		
Person's Initials	Sex	Age (at time the pro occurred) or Birth D 32		white	
		abetes, high blood pressu ficial diagnosis due to on		ese, or others) eased RA factor, HSV1, HPV, Acid	Reflux
Please list all allergies Amoxicillin, Bactrim,		oods, pollen, or others).			
List any other important drinks approximately		the person (such as smo	king, pregnancy, alcol	ol use, etc.)	
List all current prescrip Valtrex 500mg PRN	tion medications an	d medical devices being	used.		
					Continual Page
List all over-the-counted Multi Vit, Vit D, Zant		ny vitamins, minerals, su	pplements, and herba	성도 시간이 작가 얼구면 경치이네	Continual Page
☐ Go to Sec	ction E				
We will contact you on		ion E - About the Pennal information. Your name	22 10 5 5 5 5 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
Last name	ly ii we need addido	nai morriadori. Todi nai:	First name	to the public.	
(b) (6)			(b) (6)		
Number/Street (b) (6)	rimi .		City and State/Provin	ce	
Country United States			ZIP or Postal code (b) (6)		
Telephone number (b) (6)		Email address (b) (6)		Today's date (mn (b) (6)	n/dd/yy
Did you report this prof (the manufacturer)?		that makes the product	that makes the produ	me and contact information to the co ct (manufacturer) to help them evalued.  No	
Keep the product in ca		Send This Report to contact you for more	20.00g 집중(20.00 cm) 20.00g (20.00 cm)	do not send products to the FDA.	
Mail: MedWatch	rug Administration s Lane	Fax: 1-800-332-0178 (	toll-free)		
_	Tha	nk you for helping us	protect the public	realth.	
		Suit Suit			

personnel or the product caused or contributed to the event.

	Cn	 		-	-	 
- 24			-	•	-	 100

continued entry For: Tell us what happened and how it happened. (Include as many details as possible) would stop once it was washed out but my hair did not return to normal. After it came to my attention that my hair was dramatically thinner, I went to my PCP who ran multiple lab tests and then referred me to a dermatologist. There was no medical reason for my ha loss. I contacted my hair dresser who then contacted the distributor and again they told her there is no possible reason why the product would cause hair loss because it is all natural. The distributor stated they have never heard of such a reaction. I researched the product more on my own and found it to contain Formalin which, I then learned to be a form of Formaldehyde. I lost half of my hair until the hair loss finally stopped on it's own. This started in May 2013 and finally stopped at the end of August 2013. Since, my hair has started to grow back. I was psychologically distraught through out this process. I cried every time I took a shower or ran my hands through my hair. I am concerned that this product is being falsely advertised and promoted. I would have never used it if it had not been advertised as a "raw native keratin." I have included pictures of the product.

Ded to For

CONTINUED ENTRY FOR: List any relevant tests or laboratory data if you know them. (Include dates)
High RA factor which I already knew were abnormal, and have been followed by my doctor, due to testing from 2/24/12.

Back to For

CONTINUED ENTRY FOR: List all current prescription medications and medical devices being used.

Back to For

CONTINUED ENTRY FOR: List all over-the-counter medications and any vitamins, minerals, and herbal remedies being used.

Back to For

Food and Drug Administration
Center for Food Safety and Applied Nutrition
CFSAN Adverse Events Reporting System
(CAERS)

CAERS#

172434



2 - LABEL SAMPLE





## DIRECTIONS FOR SE:

Manetame on clean, damp harris medium length hair. Thicker or hair may require more sprays. me through to cover all hair. It is not to over use Manetame Wash after application. Then blow dry an that iron hair (flat iron should not weed 400 degrees). Use 1-3 times per el RNK s Manetame will dramatically singe the look & feel of all hair types ersally on hair that has not yet had a tin treatment performed on it. flat the hair will drive the keratin the hair with longer lasting follow with a sodium free Some moisturizer.



red from NE W ZEALAND

ative Kerati is a keratin
raw in nature therefore
whair more affectively
which kera in.

ACHE 33445 • 877.299988

CISAR

173153

U.S. Department of Health and Human Services

Internet Consumer Report

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011

## MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

FDA USE ONLY
Triage unit 53397

Steph   Step	Doesn't Apply Doesn't Apply Apply Apply Obesn't Apply
Steen Adverse Event   Product Problem (e.g., defects/mall/unctions)   Product Use Error   Problem with Different Manufacturer of Same Medicine   #1 Oct 28th 2013 to present   #2   Yes   No   #3   No   No   No   No   No   No   No   N	Doesn't Apply  Doesn't Apply  Doesn't Apply  Doesn't Apply  Doesn't Apply
In confidence   In confidenc	Doesn't Apply  Doesn't Apply  Doesn't Apply  Doesn't Apply  Doesn't Apply
B. ADVERSE EVENT. PRODUCT PROBLEM OR ERROR  Check all that apply.  Product Use Error Problem with Different Manufacturer of Same Medicine  Check all that apply.  Outcomes Attributed to Adverse Event (Check all that apply)  Death: (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged (Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Deate of Event (mm/dd/yyyy)  Deate of Event (mm/dd/yyyy)  A Data of this Report (mm/dd/yyyy) 12/14/2013  Describe Event, Problem or Product Use Error I have been a hairdnesser for 17 yrs and salon owner for 11 yrs now, A rep for the company Brazilian Blow out who is a friend of a close friend of mine approached me at a mutual function, The rep asked me why I didn't provide their service in my salon and how much more \$ 1 could be making etc. I hadn't heard much about this product/co, at this time for several yrs.  now. I told her I was not going to subject myself or clientele to formaldehyde exposure. This conversation went on for approx 40 min. She assured me all the hype	Doesn't Apply  Doesn't Apply  Doesn't Apply  Doesn't Apply  Doesn't Apply
Control of the company   Congenital Anomaly   Brown   Congenital Anomaly   Co	Doesn't Apply  Doesn't Apply  Doesn't Apply  Doesn't Apply  Doesn't Apply
#1 Oct 28th 2013 to present #1 Yes // No // Adverse Event Problem with Different Manufacturer of Same Medicine // Check all that apply)    Death:	Doesn't Apply Doesn't Apply After Doesn't Apply Doesn't
Product Use Error   Problem with Different Manufacturer of Same Medicine	Doesn't Apply Apply Apply Doesn't Apply
2. Outcomes Attributed to Adverse Event (Check all that apply)  Death:  Death:  Congenital Anomaly/Birth Defect  Movidalyyyy)  Congenital Anomaly/Birth Defect  Movidalization - initial or prolonged Cother Serious (Important Medical Events)  Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Describe Event (mm/bd/yyyy)  10/28/2013  Describe Event, Problem or Product Use Error  I have been a hairdresser for 17 yrs and salon owner for 11 yrs now, A rep for the company Brazilian Blow out who is a friend of a close friend of mine approached me at a mutual function. The rep asked me why I didn't provide their service in my salon and how much more \$ I could be making etc. I hadn't heard much about this product/co, at this time for several yrs.  now. I told her I was not going to subject myself or clientele to formaldehyde exposure. This conversation went on for approx 46 min. She assured me all the hype went on for approx 46 min. She assured me all the hype	Apply After Doesn't Apply Doesn't
Check all that apply    Death:	Doesn't Apply
Death:	Doesn't Apply
Life-threatening	Apply Doesn't
Life-threatening	Doesn't
Required Intervention to Prevent Permanent Impairment/Damage (Devices)   Required Intervention to Prevent Permanent Impairment/Damage (Devices)   Destroite Event (mm/dd/yyyy)	
3. Dete of Event (mm/dd/yyyy)  10/28/2013  2 Describe Event, Problem or Product Use Error  I have been a hairdresser for 17 yrs and salon owner for 11 yrs now. A rep for the company Brazilian Blow out who is a friend of a close friend of mine approached me at a mutual function. The rep asked me why I didn't provide their service in my salon and how much more \$ I could be making etc. I hadn't heard much about this product/co. at this time for several yrs. now. I told her I was not going to subject myself or clientele to formaldehyde exposure. This conversation went on for approx 40 min. She assured me all the hype	
10/28/2013  12/14/2013  E. SUSPECT MEDICAL DEVICE  1. Brand Name  2. Common Device Name  2. Common Device Name  2. Common Device Name  2. Common Device Name  3. Manufacturer Name, City and State  3. Manufacturer Name, City and State  3. Manufacturer Name, City and State  1. Brand Name  2. Common Device Name  3. Manufacturer Name, City and State  3. Manufacturer Name, City and State  3. Manufacturer Name, City and State	
5. Describe Event, Problem or Product Use Error  I have been a hairdresser for 17 yrs and salon owner for 11 yrs now. A rep for the company Brazilian Blow out who is a friend of a close friend of mine approached me at a mutual function. The rep asked me why I didn't provide their service in my salon and how much more \$ I could be making etc. I hadn't heard much about this product/co. at this time for several yrs. now. I told her I was not going to subject myself or clientele to formaldehyde exposure. This conversation went on for approx 40 min. She assured me all the hype	
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went on for approx 40 min. She assured me all the hype	
went on for approx 40 min, one assured me air the hype II	
was not true and the product did not contain 4. Model# Lot# 5. Operator of	Device
formaldehyde, it was made	essional
Catalog # Expiration Date (mm/dt//yyyy) Lay User/Pa	ation
Catalog = Capitation Date (mineraryyyy) Cay Osen/Fe	addin.
☐ Other:	
Relevant Tests/Laboratory Data, Including Dates  Through thoroughly researching this topic and my	1
ongoing health issues; I have found this to be more	-
serious than I first thought. I have read from a	(VVVV)
victim with similar symptoms that I need to find a toxicologist for specific blood tests & a industrial	325
hygienist for hair sample. Primary care DRs do   8. Is this a Single-use Device that was Reprocessed and Reused on a Patier	mt?
Yes No	
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor	
Other Relevant History, Including Preexisting Medical Conditions (e.g.,	
allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) Race: White	
F. OTHER (CONCOMITANT) MEDICAL PRODUCTS	
Medical Conditions: 2 herniated discs in back & neck issues from car accident in 2005 and fibromyalqia	
TOUR OF THE OF GOLDEN THE SAAN BUG TINIONINATATE	
Allergies: None	
Important Information: Do not smoke or drink	
1. Name and Address	
Name: Jana Johnston	
Product Available for Evaluation? (Do not send product to FDA)  Address	ij
Yes V No Returned to Manufacturer on:	
(min/bd/yyyy) City: State: ZIP.	- 14
Dispect Product(s)	
. Name, Strength, Manufacturer (from product label)  1 Name: Brazilian blow acai solution  Jana-johnston@hotmail.c	com
Strength: Original	
Manufacturer: Brazilian blow out 2. Health Professional? 3. Occupation 4. Also Reported	
Name:	
Strength:  5. If you do NOT want your identity disclosed User  Manufacturer:  to the manufacturer, place an "X" in this box:	

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

... up of amino acids and acai berry. She then said I would be a perfect candidate for the service due to my fine, highlighted, curly hair. She once again assured me by telling me consider it a conditioning treatment that will leave the most unruly damaged hair straight and shiny. I had told her about 4.5 yrs ago I had it done and it was a timesaver and my hair was nice. At this point she asked if I would be a hair model for the class to train licensed stylists how to perform this service a few days later. I went home looked up the MSDS and could not find any formaldehyde compound so I agreed. This was the worst mistake of my life! The day of the class I showed up at the Hilton in LaJolla CA. I was bent over a public bathroom sink to wash 1/2 my head for the before and after pics. for their website. I had reviewed the steps of the service on their website the night before to familiarize myself with the procedure. During the application my eyes, nose and throat were burning, the stylist who did the service told me to close my eyes. After the class left and they got their photo I was told time was running late and the Co. started packing up the merchandise they hadn't sold. I was expecting the next step whic was to rinse the chemical out of my hair. The stylist told me to rinse it myself when I got home but not to shampoo it. I questioned him on the safety of this and he said I could safely leave it in for "a few days and it would be fine." Hesitantly I said ok and asked to see a mirror. The rep and the stylist kept commenting on how great it looked. I saw that my hair looked very dull, dry, and the color had been stripped out. I told the rep. that this was supposed to do the opposite, she claimed it looked great. I left and went to my regular monad scheduled accupuncture apt. This is when I really started noticing a bad reaction. While driving to my apt I felt like mt neck and scalp were on fire. Apon getting to my destination I felt dizzy and nauseous. Within 4.5 hrs getting this treatment done I got home and rinsed and conditioned as directed. I had blisters on my scalp and back of neck. My hair felt like hay and was way thinner than normal. I didn't even dry my hair due to the pain on my scalp. The next day I had all of the same symptoms and started vomiting up to 3xs a day. This proceeded with chunks of hair broken off and flu like symptoms. I missed a week of work, too out of it to leave my bed. At this point I realized there was something linking the illness with the use of this product and it's shampoo conditioner and mask as directed. I started documenting my hair loss and varying health concerns via numerous pictures and daily journal entries. I did contact the rep 4 days post treatment to tell her I had blisters and my hair was chemically burned off. She asked to see the few pics. I had at the time and called back horrified! She finally told me this actually happened to her the 1st weeks of her employment with this co. And said he had used way to high of heat for my hair which caused this reaction and no cape to protect my skin. Fast forward to today 5 weeks later i haven't felt myself since I had this keratin treatment done! I'm scared with all the health issues arising including; nose bleeds, flu that never ends, burning and red rashes after showering, muscle pain, weight loss, headaches, insomnia, confusion, shaking, anxiety attacks

#### 8.5 Relevant Tests/Laboratory Data, Including Dates (continued)

... not deal with chemical poisoning, or even know the correct tests to order for formaldehyde. I am now trying to figure out how to afford the thousands of \$ of tests my insurance won't cover.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

,,, 612

Internet Health Professional Report

Form Approved: OM8 No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

For VOLUNTARY reporting of adverse events, product problems and

A. PATIENT IN 1. Patient Identifier	2. Age at Time of Event or	3. Sex	4. Weight	2. #1	Once or Amount		after Topic	
b) (6)	Date of Birth: 37 Years	✓ Female  ☐ Male	155 <sub>lb</sub>	#2		care		
In confidence  B. ADVERSE   Check all that apply:	EVENT, PRODUCT PR		RROR	3. Da	tes of Use (If unknown best estimate)	vn, give duratio		ent Abated After Use ped or Dose Reduced?
Adverse Even	t Product Problem (e		4 10	1100	nce oct still	in hair		Yes No Doesn
2 Outcomes Attribe (Check all that app	157	ability or Parmanen	Damaon	#1	gnosis or Reason f This was suppose smooth frizz, ar	ed to condit	ion, 8 Ev	Yes No Doesn Apply ent Responsed After introduction?
Death: Disability or Permanent Damage  (mm/dd/yyy)  Life-threstening Congenital Anomaly/Birth Defect		#2	#2			#1 Yes No Doesi		
	- initial or prolonged 🕢 Other vention to Prevent Permanent		and the second section of the second section of	6. Lot # 7. Expiration Date #1			Yes No Doesn Apply OC # or Unique ID	
3. Date of Event (mi 10/28/2013		te of this Report (	mm/dd/yyyy)	#2	SUSPECT MEDI	#2 CAL DEVIC	E	
5 Describe Event, I Scalp & nape	Problem or Product Use Em	or ered while a		1. Bre	nd Mame azilian blow o			~.
model. My ha hairline by	ormed a Brazilian bl air continually brea the roots. Major he cose, eyes, and sinu	ks, some aro	und my s since day		mmon Device Name iginal		DEC	<b>CTU</b> 1 <b>6</b> 2013
of service nose, eyes, and sinus burning. But a majority 4 days following. Including dizziness, flusymptoms, sore throat, nose bleed, chest tightness, insomnia, nausea, cognitive issues, headaches, random metallic taste in mouth, burning bumps & redness on the service of the			Br	nufacturer Name, C Azilian blow o S Angeles CA	out		<b>10</b> 2013	
legs after shower, fatigue, muscle pain, hot & cold tingling hands, and anxiety. Many of these symptoms are daily, I haven't felt		4 Mo	del #	Lot#		5. Operator of Device  Health Professiona		
		Cat	alog#	Expiratio	Expiration Date (mm/dd/yyyy) Lay User/			
5. Relevant Tests/Laboratory Data, including Dates		Ser	ial#	Other #		Cosmetologis		
				6. If In	nplanted, Give Date	(mm/dd/yyyy)	7. If Explanted	, Give Date (mm/dd/yyyy)
					his a Single-use Der Yes \[ \] No	vice that was R	Reprocessed and	Reused on a Patient?
Other Relevant Hi	story, Including Preexisting	Madical Condition	04 /0.0	9. H.Y	es to item No. 8, Ente	r Name and Add	iress of Reprocess	ior
No allergies	gnancy, smoking and alcohol non amoker non dri	use, liver/kidney pr	oblems, etc.)	F. 0	- US THER (CONCO	MITANT) MI	EDICAL PROD	DUCTS
prior,				Produ I wa	ct names and thera s using the Br serum, daily s	py dates (exclusive azilian Bl	ide treatment of ev Low Out after	
					EPORTER (See	confidentia	lity section on	back)
PRODUCT A Product Available for	VAILABILITY or Evaluation? (Do not send )	product to FDA)	11		ne: (b) (6) ress		7	
Yes No	Returned to Manufacture	er on: (mm	(ddyyyy)	City			State:	ZIP:
	lanufacturer (from product la an Blow Out	ibel)		Phone			E-mail (b) (6)	
	mai azilian blow out			1 20.00	th Professional?		Health Professiona	
Strength; Manufacturer:					ou do NOT want your ne manufacturer, place			User Facility Distributor/Importer
	14 10 61		I managitude on a de	of a of a se at	and the state of the state of	all me they would	d any lead at ac-tal	history to the many

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

... myself in over a month and a half! It's believed the flat iron was used at too high of heat along with the fact that I was sent home with the chemical in my hair to rinse myself.

14....

BRAZILIAN BLOWOUT 28001 DOROTHY DR AGOURA HILLS, California 91301

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 173153.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Enclosure

#### [Close]

#### **FACTS** Interface

FACTS Complaint #135401 (CAERS )	F1734U4)		
Complaint Date	12/24/2013	Complaint Source	Consumer
Accomplishing District	NYK-DO	Complaint Status	Archived
How Received	Telephone		

Name	(b) (6)	Work Phone	
Address	(b) (6)	Home Phone	(b) (6)
		Source POC Name	
City	(b) (6)	Source Phone	
State	(0) (6)		
Zip	(b) (6)		
Province			
Country	US		
Mail Code			

#### Complaint / Injury

**Complaint Description** 42 year old female complainant with no known allergies and no medical conditions believes Peter Coppola Keratin Smoothing Treatment is caus for her symptoms. Complainant worked at a salon for 1 year and 2 months and was a very active person. From 12/09 to 8/11 complainant serviced clients with smoothing treatments on an average of twice per week. After about a year, complainant developed symptoms of coughing up brownish/yellowish flem, a continuous cough, raspy voice and chest pains. Complainant noted that other stylist were experiencing similar symptoms and determined that symptoms must be related to product in question due to the amount of excess fumes involved with the smoothin treatments. Complainant discontinued use of product in question in 08/11 however her symptoms persist. In 09/12 complainant was diagnosed with auto immunune disorder. She has persistent chest pains and requires steam to improve her breathing. She has also developed swelling in her legs and was recently approved for disability due to her ongoing conditions.

Adverse Event Result	Life Threatening
Adverse Event Date	08/2011
e Notify EIO/EMOPS?	Yes
Notification Date	12/24/2013
Attended Health Professional?	Unknown
Required Hospitalization?	No
Emergency Room/ Outpatient Visit?	No
Reported Complaint To?	FDA
g	
Need Additional/	
FDA Contact?	

#### Remarks

Complaint Symptoms				
Symptom Name	Duration	Remarks		
Local swelling	null null	Swollen legs		
Chest Pain	null null	Continuous pain		
Coughing	null null	Persistent cough		
Excessive phlegm production	null null	Coughing up brownish/yellowish flem		
Difficulty breathing	null null	Has labored breathing and needs steam to help relieve		
NEC - Identify in Remarks	null null	Auto immune disorder, raspy voice		

#### Health Care Professional

There is not health care information listed for this consumer complaint report.

Product and Labeling			
Brand Name	Peter Coppola		
Product Name	Keratin Smoothing	Treatment	
FDA Product Code	53ED03	Qty/Unit	

UPC Code	UNK	Package	Bottle
Exp/Use By Date	UNK	Lot/Serial	UNK
Product Used?	Yes	Purchase Date	UNK
Date Used?	12/09 - 08/11	Amount Consumed/Used	UNK
Amount Remained	N/A	Date Discontinued	08/2011
Country of Origin		Imported Product?	No
Retailer Name		Label Remarks	

#### Manufacturer/Distributor

There is no firm information listed for this consumer complaint report.

Initial Evaluation	/ Initial Disposition		
Initial Evaluation	Insuffici. Info, unable to evaluate	Initial Disposition	Closed w/o further Investigation
Disposition Date	01/23/2014		
_			

#### Remarks

12/2013\*\*\*Customer Service, 855-426-7765, awaiting vendor response\*\*\*\*Per customer service. Their product is a new line just lauched 6/13. It has been many times confused with old line. The old line is via Keratin Complex, HQ at 888-409-4445.\*\*\* 1/6/14 Called number provided for old line. Awaiting vendor response\*\*\*\* 1/13/14 Called again. Second request\*\*\*Per Marino Salvano, 888-409-4445 X334, complaints are forwarded via the FDA CAERS System. The company will not release information via phone request.\*\*\*Sent email to CFSAN for their assistance.\*\*\*\* 1/17/14 Sent second request for assistance via email. Awaiting reply/assistance.\*\*\* 1/23/14 To date, no response from CFSAN and company was uncooperative.

Problem Keyword	Problem Keyword Details		
Reaction	Developed persistent cough, coughs up flem, chest pains, raspy voice, swollen legs		

Cosmetic ID #25183 DOB			
		Age	42
Gender	Female	Race	White
Application Place	Salon/SPA	Reason for Use	Hair Preparations (Non-Coloring)
Application Site	Hair	Other Products?	
Directions			
Jnknown			
Directions Followed?	Yes	Product Duration	
Frequency of Use	Other	Reaction Site	Chest
Product Use in Off-Label Manner?	No	Off-Label Manner Des	sc
Warning Statement on Label?		Warning Statements? Unknown	<b>,</b>
Preexisting Conditions?	No	Treatment	Physician
Current Status	Worsening		
Medical Diagnosis		Medical Treatment	
Auto Immune Disorder		On going	

#### Adverse Events

product

There is no adverse event information listed for this consumer complaint report.

[Close]

# KERATINCOMPLEX.

March 24, 2014

173463-001

CFSAN / CEARS Staff (HFS-11), 5100 Paint Branch Parkway College Park, MD 20740

Re: Keratin Complex CFS Notice #173404/173463

Dear CFSAN / CAERS Staff:

This letter responds to your request for a response to your inquiry letter of February 6, 2014, relating to the salon professional health concerns claimed to be related to use of our products.

Please be advised that Keratin Complex has an extensive and detailed training and certification program for salon professionals who use our products. This program must be fully deployed and the certification process completed before salon professionals may use our products. These programs are specifically designed to avoid any sensory or dermal irritation that may arise from the use of our products. We are confident, based on our experience and the level of depth of these programs, that when they are followed, the risk of the kind of exposure concerns expressed in the noted communication are extremely low if not non-existent.

As well, Keratin Complex maintains a strict monitoring program in support of these training and certification processes, such that if it comes to our attention through our distribution network that any salons or salon professionals using our products are not compliant with our training and certification programs, we remove product from those salons until compliance is achieved. And we work closely with our distribution and salon partners to ensure that only the highest standards of employee and consumer health and safety are maintained.

In addition, we have an extensive internal system for tracking complaints regarding our products, and which such complaints contain sufficient information for us to communicate directly with the location where the complaint has arisen, we interact directly with salons in those instances to ensure that health and exposure concerns are addressed and do not re-occur.

Page 1 of 2

114MR 18



Furthermore, as you are likely aware, there are a wide array of chemicals present in products in use on a regular basis within the salon environment which may cause the kind of concerns reflected in the noted communication.

In addition to these extensive programs and policies, we are aware that we must always exercise the highest levels of diligence in regards to consumer and salon professional health and safety. As a consequence, we are always looking at ways in which we can continuously improve our programs and procedures in this regard. Please know that we will continue to provide the highest level of attention to these matters. We appreciate your inquiry, and we would welcome the opportunity to provide you with more information as needed.

Sincerely,

Marina Salzano

Compliance and Regulatory Manager Keratin Complex Smoothing Therapy

Page 2 of 2

Keratin Complex 6400 Congress Ave Suite 2000 Boca Raton, Florida 33487

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 173404.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Enclosure

## MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

	FDA USE ONLY	
Triage unit sequence #	537447	

A PATIENT	INFORMATION				2. Dose or A	mount	Frequer	cv Route	
1. Patient Identif	ier 2. Age at Time of	Event or 3. Se	ex	4. Weight	7#1				
(b) (6)	Date of Birth:	1	/ Female	175 lb				11 / 1	
	(b) (6)	-   [	_ □ Male	or kg	#2			11/5	
In confidence	E EVENT, PROD		-( 111135		3. Dates of Use	//f unknown	nive duration	fromto 5 Euro	nt Abated After Use
Check all that app		OCTPROBL	EWI OR E	RROR	(or best estim	iáte)	give duradori)		ed or Dose Reduced?
1. Adverse E		roblem (e.g., del	fects/malfund	ctions)	#1 01/11/201	14 -		#1	Yes No Does
Product Us	se Error Problem v	with Different Ma	anufacturer	of Same Medicine	#2			#2	Yes No Does
2 Outcomes Att	tributed to Adverse E	vent			4. Diagnosis or #1 hair tre		Jse (Indication		nt Reappeared After
Death:		Disability o	or Permanent	Damage	11 10 20 123	7207		Rein	ntroduction?
Life-threats	(mm/dd/yyyy)	Connenital	I Anomaly/Bi	th Defect	#2			#1	Yes No Does
	ition - initial or prolonge		the selection of the second		6. Lot#	15	. Expiration	Date #2	Yes No Dos
_	ntervention to Prevent F				#1		11	9. NDC	# or Unique ID
3. Date of Event	t (mm/dd/vyvy)	4. Date of the	his Report (	mm/dd/yyyy)	#2	1	12		
01/11/20	CONTRACTOR STATE	01/23/	CALLES CAR CHARACTER		E. SUSPEC	T MEDICA	L DEVICE		
5. Describe Eve	nt, Problem or Produc	ct Use Error			1. Brand Name				
	razilian blowou 1th, 2014. On M								
feeling u	nwell and my as	thma starti	ng flari	ng(I have a	2. Common De	vice Name			
	f asthma). By W work and have				1			CTU	
27th, 201	4. I have been	to the doct	or sever	al times will	3. Manufacture	r Name, City	and State	100000	
	been on steroid improvement. I							JAN 2 4 20	114
	improvement. I connection betw				3			- 2 20	114
	blowout. I was lungs. The sty				4 Model#		Lot#		5. Operator of Device
my eyes a	s she	New April 1		- 1					Health Profession
					Catalog #	_	Expiration	Date (mm/dd/yyy)	Lay User/Patient
									Other:
6. Relevant Test	ts/Laboratory Data, In	cluding Dates			Serial #	-	Other#		
					100				100
					6. If Implanted,	Give Date (m	m/dd/yyyy)	7 If Explanted,	Give Date (mm/dd/yyyy
							e that was Re	processed and R	leused on a Patient?
					Yes Yes to item		ame and Add	ess of Reprocess	7
					l o licios io iiolii	No. o, Emer N	anne ano Aou	esa or reprocess	
<ol><li>Other Relevar allergies, race,</li></ol>	nt History, Including P , pregnancy, smoking a	reexisting Medi and alcohol use, li	cal Condition	ns (e.g., roblems, etc.)					
Race: Whit					F. OTHER (	CONCOM	TANT) ME	DICAL PROD	UCTS
	onditions: asth			rnia,	Product names	and therapy	dates (exclud	de treatment of eve	ent)
anxiety,	depression, int	erstitial c	ystitis						
Allergies	: shellfish(iod	line), eryth	romyocin	, codeine					
Important	Information:			20	d REPORT	FR (See co	onfidential	ty section on	back)
	SMARKS (1747) 161			184.02	1. Name and A			- Josephon On	
	T AVAILABILITY	not cond and	of to EDAY		Name: (b) (6		0 6		
	ole for Evaluation? (Do			1 1	Address: (b)	(6)			
Yes N		vianulacturer on:	(mn	/dd/yyyy)	0.4			Curt Mile	TID. YET YOU
	PRODUCT(S)				City: (b) (6)  Phone #			State (a) (6 2	ZIP: (b) (6)
And the second	th, Manufacturer (from cilian Blowout	n product label)			I Holle W			(b) (6)	
Strength:	TTTUL DIOWOUL							77.00	
Manufacturer	,				2. Health Profes		Occupation		4. Also Reported to:
#2 Name:					Yes		TANK THE TOTAL		Manufacturer User Facility
Strength: Manufacturer:					5. If you do NOT to the manufa	want your ide			Distributor/Import
TI THE STATE OF TH							OF THE LANCE		

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

... straight ironed it. I had headaches for the first week as well. The headaches have gone away but now I am still short of breath and lethargic. I am going to contact my stylist to see what options I have to get this chemical out of my hair asap!

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
... omeprazole, zanaflex

... omeprazole,zanaflex

OTC Meds: fish oil, vitamin D, iron, vitamin E, multivitamin

Brazilian Blowout 28001 Dorothy Dr Agoura Hills, California 91301-2609

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 173431.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Enclosure

## MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

	FDA USE ONLY	
Triage unit sequence #	537637	

	INFORMATION		1, 10, 12	2. [	lose or Amount	Frequer	ncy Route	0	
1. Patient Identifie (b) (6)	2. Age at Time of E Date of Birth:		4. Weight	#1					
<i>3</i> /( <i>0</i> )	30 Years	✓ Female	107 <sub>1b</sub>	#2 [					
In confidence	(b) (6)	☐ Male	or kg						
	EVENT, PRODU	CT PROBLEM OR E	RROR		es of Use (If unknow	n, give duration)		vent Abated	
Check all that apply	The second of the same	State of The State		1000	best estimate) /15/2014 - 01/	15/2014	1000	pped or Dose	
1. Adverse Eve	and the second s	oblem (e.g., defects/malfun	The second secon	#2	715/2014 - 01/	13/2014	#1	Yes 1	No LAPP
	_	th Different Manufacturer	of Same Medicine	7-0	gnosis or Reason fo	r Hen /Indicatio	#2	Yes n	No Doe
(Check all that a	buted to Adverse Eve pply)	ent			or hair straigh		8. E	vent Reappe	ared After
Death:		Disability or Permaner	nt Damage	#2				eintroduction Yes N	
Life-threateni	(mm/dd/yyyy) ing	Congenital Anomaly/B	irth Defect	#2					App
☐ Hospitalization	on - initial or prolonged	Other Serious (Importa	ant Medical Events)	6. Lot	#	7. Expiration	Date #2	Yes I	Vo Doe
		rmanent Impairment/Dama		#1		#1	9. N	DC # or Uniq	
3. Date of Event (	Charles of the Second	4. Date of this Report	(mm/dd/yyyy)	#2		#2			
01/15/201		01/25/2014			USPECT MEDI	CAL DEVICE			
	, Problem or Product	Use Error eratin treatment.	During my	1 Bra	nd Name			CI	Ð
consult, th	ne stylist told	me it was natura	L, good for	1 -				~!!	W
		clients love it. tin treatments and		2. Cor	nmon Device Name			IAN o-	
like a good	d option. Durin	g the treatment my	y eyes					JAN 27	2014
		oint where they st		3 Mar	ufacturer Name, Ci	ty and State	1		
majority of	f the time I was	s there. The styli	ist said "oh	-					
		our eyes closed as O minutes that the						-3.	
had to sit	on my hair, the	e stylist just dis		4. Mod	lel#	Lot#		The second	ator of Devi
ii she didr	n't want to be					1		L Heal	Ith Professio
				Cat	alog #	Expiration	Date (mm/dd/y	(YYY) Lay	User/Patient
1				81				Othe	er:
	Laboratory Data, Incl	uding Dates		Ser	al#	Other#			
NA			,diame	57					
				6. If Im	planted, Give Date	(mm/dd/yyyy)	7 If Explante	d, Give Date	(mm/dd/yyy)
					is a Single-use Dev	ice that was Re	processed and	d Reused on	a Patient?
				-	Yes No	Alama a - A A A A			a Williams
				9. 11 46	s to Item No. 8, Enter	Name and Add	ess of Reproces	ssor	
Allerania a market a	the state and the first state of the state of the	existing Medical Condition	CALL STREET, S						
allergies, race, p	African Americ			F. 0	THER (CONCO	MITANT) ME	DICAL PRO	DUCTS	
	militarian imperio								
Race:Black	nditions: None				ct names and thera		le treatment of e	, and with	
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Race:Black, Medical Cor Allergies: Important 1  C. PRODUCT Product Available Yes No	None Information: None  AVAILABILITY for Evaluation? (Do n	not send product to FDA)	n/dd/yyyy)	G. R. 1. Nam Nam Add	EPORTER (See see and Address see 1(b) (6) ress. (b) (6)	y dates (exclud	ty section o	n back)	G.
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Race:Black, Medical Cor Allergies: Important I  C. PRODUCT Product Available Yes V No D. SUSPECT Name, Strength,	None  None  Information: Non  AVAILABILITY for Evaluation? (Do n  Returned to Ma  PRODUCT(S) , Manufacturer (from p	not send product to FDA) nulacturer on: (mr		G. R. 1. Nam Nam Add City	EPORTER (See the and Address the 1(b) (6) ress.(b) (6)	y dates (exclud	ty section of State: (0) (6) E-mail	n back)	6)
Race:Black, Medical Cor Allergies: Important I  C. PRODUCT Product Available Yes No D. SUSPECT T Name, Strength,	None  None  Information: Non  AVAILABILITY for Evaluation? (Do n  Returned to Ma  PRODUCT(S) , Manufacturer (from p	not send product to FDA) nulacturer on: (mr		G. R. 1. Nam Nam Add	EPORTER (See the and Address the 1(b) (6) ress.(b) (6)	y dates (exclud	ty section of	n back)	6)
Race:Black, Medical Cor Allergies: Important I  C. PRODUCT Product Available Yes No D. SUSPECT Name, Strength, Manufacturer:	None  None  Information: Non  AVAILABILITY for Evaluation? (Do n  Returned to Ma  PRODUCT(S) , Manufacturer (from p	not send product to FDA) nulacturer on: (mr		G. R. 1. Nam Add City Phone (b) (	EPORTER (See the and Address the I(b) (6) ress.(b) (6) #6)	oy dates (exclud	ty section of State: (0) (6) E-mail	zip- (b) (i	ported to:
Race:Black, Medical Cor Allergies: Important I  C. PRODUCT Product Available Yes V No D. SUSPECT Name, Strength, #1 Name: Kerat. Strength:	None  None  Information: Non  AVAILABILITY for Evaluation? (Do n  Returned to Ma  PRODUCT(S) , Manufacturer (from p	not send product to FDA) nulacturer on: (mr		G. R. 1. Nam Nam Add City Phone (b) (	EPORTER (See the and Address the (b) (6) ress.(b) (6) #6)	confidentiali	State: (a) (b) (6)	zip- (b) (i	

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

... around the stuff. That night I went home and noticed some of the keratin mixture that had dried on the back of my neck so I just wiped it off with a wet tissue. The very next day a rash started to appear on the back of my neck. They were moist raised welts and were there for the next 3-4 days until it started to go down and dry out. I then did some more research and looked specifically for adverse reactions from keratin treatments. I was shocked at what I found, especially the fact about the treatments not being "natural" or chemical-free. I reached out to the Salon owner and she assured me that she only uses the best items at her salon and that she has had no other complaints. I met again with the stylist that worked on my hair and after looking at my neck she said it was just an allergic reaction and that the neck is usually a sensitive area. She also told me that they called the supplier and that there is nothing wrong with the keratin mixture and there are no chemicals. I asked if they had a list of the ingredients and she said no. So basically, the salon is just taking their word for it. I am not someone who has sensitive skin and I have no known allergies to anything. Something just didn't sit right with me about the whole situation. They couldn't explain why my eyes were burning and they didn't even bother to tell me about it beforehand. If I went to a doctor that gave me medicine and knew about side affects related to it and didn't bother to tell me, I wouldn't trust that doctor. At this point, I think the Salon is dismissing my experience there. Something is wrong with that mixture. Something that is "natural" shouldn't burn my eyes to the point where I can't even keep them open or cause my skin to welt. It has been about a week and a half since I had the treatment. The rash is now gone and so far no other anomalies have occurred.

#### [Close]

#### **FACTS Interface**

FACTS Complaint #135401 (CAERS #	173463)		
Complaint Date	12/24/2013	Complaint Source	Consumer
Accomplishing District	NYK-DO	Complaint Status	Archived
How Received	Telephone		

Name	(b) (6)	Work Phone	
Address	(b) (6)	Home Phone	(b) (6)
		Source POC Name	
City	(b) (6)	Source Phone	
State	(0) (6)		
Zíp	(b) (6)		
Province			
Country	US		
Mail Code			

#### Complaint / Injury

**Complaint Description** 42 year old female complainant with no known allergies and no medical conditions believes Peter Coppola Keratin Smoothing Treatment is caus for her symptoms. Complainant worked at a salon for 1 year and 2 months and was a very active person. From 12/09 to 8/11 complainant serviced clients with smoothing treatments on an average of twice per week. After about a year, complainant developed symptoms of coughing up brownish/yellowish flem, a continuous cough, raspy voice and chest pains. Complainant noted that other stylist were experiencing similar symptoms and determined that symptoms must be related to product in question due to the amount of excess fumes involved with the smoothin treatments. Complainant discontinued use of product in question in 08/11 however her symptoms persist. In 09/12 complainant was diagnosed with auto immunune disorder. She has persistent chest pains and requires steam to improve her breathing. She has also developed swelling in her legs and was recently approved for disability due to her ongoing conditions.

Adverse Event Result	Life Threatening
Adverse Event Date	08/2011
se Notify EIO/EMOPS?	Yes
Notification Date	12/24/2013
Attended Health Professional?	Unknown
Required Hospitalization?	No
Emergency Room/ Outpatient Visit?	No
Reported Complaint To?	FDA
Need Additional/ IS FDA Contact?	

#### Remarks

Complaint Symptoms					
Symptom Name	Duration	Remarks			
Local swelling	null null	Swollen legs			
Chest Pain	null null	Continuous pain			
Coughing	null null	Persistent cough			
Excessive phlegm production	null null	Coughing up brownish/yellowish flem			
Difficulty breathing	null null	Has labored breathing and needs steam to help relieve			
NEC - Identify in Remarks	null null	Auto immune disorder, raspy voice			

#### Health Care Professional

There is not health care information listed for this consumer complaint report.

Product and Labeling			
Brand Name	Peter Coppola		
Product Name	Keratin Smoothing	Treatment	
FDA Product Code	53ED03	Qty/Unit	

000001

UPC Code	UNK	Package	Bottle
Exp/Use By Date	UNK	Lot/Serial	UNK
Product Used?	Yes	Purchase Date	UNK
Date Used?	12/09 - 08/11	Amount Consumed/Used	UNK
Amount Remained	N/A	Date Discontinued	08/2011
Country of Origin		Imported Product?	No
Retailer Name		Label Remarks	

#### Manufacturer/Distributor

There is no firm information listed for this consumer complaint report.

Initial Evaluation / Initial Disposition			
Initial Evaluation Insuffici. Info, unable to evaluate	Initial Disposition	Closed w/o further Investigation	
Disposition Date 01/23/2014			

#### Remarks

12/2013\*\*\*Customer Service, 855-426-7765, awaiting vendor response\*\*\*\*Per customer service. Their product is a new line just lauched 6/13. It has been many times confused with old line. The old line is via Keratin Complex, HQ at 888-409-4445.\*\*\* 1/6/14 Called number provided for old line. Awaiting vendor response\*\*\*\* 1/13/14 Called again. Second request\*\*\*Per Marino Salvano, 888-409-4445 X334, complaints are forwarded via the FDA CAERS System. The company will not release information via phone request.\*\*\*Sent email to CFSAN for their assistance.\*\*\*\* 1/17/14 Sent second request for assistance via email. Awaiting reply/assistance.\*\*\* 1/23/14 To date, no response from CFSAN and company was uncooperative.

Problem Keyword	Problem Keyword Details
Reaction	Developed persistent cough, coughs up flem, chest pains, raspy voice, swollen legs

Cosmetic			
Cosmetic ID #(b) (6)			
DOB		Age	42
Gender	Female	Race	White
Application Place	Salon/SPA	Reason for Use	Hair Preparations (Non-Coloring)
Application Site	Hair	Other Products?	
Directions Unknown			
Directions Followed?	Yes	Product Duration	
Frequency of Use	Other	Reaction Site	Chest
Product Use in Off-Label Manner?	No	Off-Label Manner Desc	
Warning Statement on Label?		Warning Statements? Unknown	
Preexisting Conditions?	No	Treatment	Physician
Current Status	Worsening		
Medical Diagnosis		Medical Treatment	
Auto Immune Disorder		On going	
Remarks			
Product used an average of twice per week*	"Per complainant, she	followed product directions	as well as received training for application of

### Adverse Events

product

There is no adverse event information listed for this consumer complaint report.

[Close]

# KERATINCOMPLEX.

March 24, 2014

173463-001

CFSAN / CEARS Staff (HFS-11), 5100 Paint Branch Parkway College Park, MD 20740

Re: Keratin Complex CFS Notice #173404/173463

Dear CFSAN / CAERS Staff:

This letter responds to your request for a response to your inquiry letter of February 6, 2014, relating to the salon professional health concerns claimed to be related to use of our products.

Please be advised that Keratin Complex has an extensive and detailed training and certification program for salon professionals who use our products. This program must be fully deployed and the certification process completed before salon professionals may use our products. These programs are specifically designed to avoid any sensory or dermal irritation that may arise from the use of our products. We are confident, based on our experience and the level of depth of these programs, that when they are followed, the risk of the kind of exposure concerns expressed in the noted communication are extremely low if not non-existent.

As well, Keratin Complex maintains a strict monitoring program in support of these training and certification processes, such that if it comes to our attention through our distribution network that any salons or salon professionals using our products are not compliant with our training and certification programs, we remove product from those salons until compliance is achieved. And we work closely with our distribution and salon partners to ensure that only the highest standards of employee and consumer health and safety are maintained.

In addition, we have an extensive internal system for tracking complaints regarding our products, and which such complaints contain sufficient information for us to communicate directly with the location where the complaint has arisen, we interact directly with salons in those instances to ensure that health and exposure concerns are addressed and do not re-occur.

Page 1 of 2

114 MR X



Furthermore, as you are likely aware, there are a wide array of chemicals present in products in use on a regular basis within the salon environment which may cause the kind of concerns reflected in the noted communication.

In addition to these extensive programs and policies, we are aware that we must always exercise the highest levels of diligence in regards to consumer and salon professional health and safety. As a consequence, we are always looking at ways in which we can continuously improve our programs and procedures in this regard. Please know that we will continue to provide the highest level of attention to these matters. We appreciate your inquiry, and we would welcome the opportunity to provide you with more information as needed.

Sincerely,

Marina Salzano

Compliance and Regulatory Manager Keratin Complex Smoothing Therapy

Page 2 of 2

Keratin Complex 6400 Congress Ave Suite 2000 Boca Raton, Florida 33487

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 173463.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Enclosure

The FDA Safety Information and

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

Adverse Event	,			In process		Feer		
A. PATIENT IN	FORMATION  2. Age at Time of Event or	3. Sex	4. Weight	2. Dase or Ame	ount	Frequency	Route	
(b) (d)	Date of Birth:		255 lb					
	36 Years (b) (6)	✓ Female		#2				
In confidence	(0) (0)	Male	or kg	I TO THE T				
B. ADVERSE I	EVENT, PRODUCT PR	OBLEM OR E	RROR	3. Dates of Use (I (or best estimate		ve duration) fro		t Abated After Use d or Dose Reduced?
1. Adverse Even	t Product Problem (e	.g., defects/malfun	ctions)	#1			#1 🗸	res No Does
	rror Problem with Differ			#2			#0 [7]	Yes No Does
	uted to Adverse Event			4. Diagnosis or R		Water Committee of the	10.5	Appl
(Check all that ap)		bility or Permanen	Damage	#1 Hair smoot	thing produ	100		t Reappeared After roduction?
	mm/dd/yyyy)			#2			#1 🗸	Yes No Does
Life-threatening		genital Anomaly/Bi		6. Lot#	7	Expiration Dat	#2 🗆	res No Does
	<ul> <li>initial or prolonged  Other</li> <li>vention to Prevent Permanent</li> </ul>	The state of the s	The second secon	#1	#1			# or Unique ID
3. Date of Event (mi		te of this Report		#2	#2		- B. N.D.C.	or ornque to
02/22/2014	The state of the s	24/2014	ilina ddiyyyy)	E. SUSPECT	MEDICAL	DEVICE		7 7
Seat 187 - The Carrier Land	Problem or Product Use Erro	and the second		1. Brand Name	and the second s	CHECK STATE		
	, nose running and		aring loss	15-0-1-1				
				2. Common Device	ce Name			
								Con
				3. Manufacturer N	Jama City an	d Ctata		MAN (M)
				S. Mandiacturer P	vame, city an	io state	60	AR 25 2014
							742	n 2 5 2014
				4. Model#		Lot#		5. Operator of Device
					- 1			Health Profession
				Catalog #		Evolration Da	te (mm/dd/yyyy)	Lay User/Patient
				Catalog #		Expiration oa	ie (minutaryyyy)	
Relevant Tosts/I	aboratory Data, Including Da	atne				25		Other:
- 112/31 diji 14000/2	and a start of the	2,00		Serial#		Other#		
				La Taux				
				6. If Implanted, G	ive Date (mm	/dd/yyyy) 7	If Explanted, G	live Date (mm/dd/yyyy
						hat was Repro	cessed and Re	used on a Patient?
				9. If Yes to Item No		ne and Address	of Reprocessor	
		The Will State of		I The second record record	. A CONTROL FERRI	and Abdids	- reprocessor	
allergies, race, pre	istory, Including Preexisting egnancy, smoking and alcohol	Medical Conditions use, liver/kidney po	ns (e.g., robiems, etc.)					
Race: White				F. OTHER (C	ONCOMIT	ANT) MEDI	CAL PRODU	ICTS
Medical Cond	ditions: premature a	trial contra	ctions	Product names an	nd therapy da	ates (exclude b	ealment of even	Ų
Allergies: h	oananas, avocado, me	lon, shellfi	sh					
Important In								
important in	TOTING LIDIN.			G. REPORTER	R (See con	fidentiality	section on b	ack)
C DDODUCE	VAIL ADIL ITY			1. Name and Add		Acceptable of the Control of the Con		
C. PRODUCT A	VAILABILITY or Evaluation? (Do not send	norther to EDA		Name: (b) (6)				
Yes No	Returned to Manufacture			Address (b) (6)	1900			
	lined .	(ma	n/dd/yyyy)	City/fo/fo			State (P) 6 ZI	P/hV/6)
D. SUSPECT P	AND THE RESERVE OF THE PARTY OF	hell.		City (b) (6) Phone #	8	E	mail	L(n) (n)
Name, Strength, I Name prazil	Manufacturer (from product la Lan blowout	spel)		(b) (6)		0.00	) (6)	
WARRED.								
Strength:				2. Health Profess	ional? 3. Oc	cupation	4	Also Reported to:
Manufacturer				T				[T] stone to
				Yes No	(4)	Mar attacks and		☐ Manufacturer ☐ User Facility

#### [Close]

#### **FACTS Interface**

FACTS Complaint #134917 (CAERS #175122)			
Complaint Date	11/08/2013	Complaint Source	Consumer
Accomplishing District	NWE-DO	Complaint Status	Archived
How Received	Telephone		

Name	(b) (6)	Work Phone	(b) (6)
Address	(b) (6)	Home Phone	(b) (6)
		Source POC Name	
City	(b) (6)	Source Phone	
State	(6) (6)		
Zip	(b) (6)		
Province			
Country	US		
Mail Code			

#### Complaint / Injury Complaint Description

Consumer states that she is a professional hairdresser and was hospitalized twice approximately one week after giving a keratin smoothing treatment to a client. Consumer went to the emergency room on 10/21/2013 complaining of difficulty breathing, and a productive cough with blood in the sputum. Consumer was treated with a cough suppressant and antibiotics and then released. Consumer returned to the emergency room the next day complaining of worsening symptoms. At that time she was admitted to the hospital. Consumer was hospitalized from 10/22/2013 until 10/26/2013. Consumer states that while hospitalized a lung biopsy was performed which indicated blood, fluid and unidentified white matter. Additionally she states that her liver function tests came back elevated. CT scan and xrays were normal. She is scheduled for a pulmonary function test next month

Adverse Event Result	Life Threatening
Adverse Event Date	10/21/2013
Notify EIO/EMOPS?	Yes
Notification Date	11/08/2013
Attended Health Professional?	Yes
Required Hospitalization?	Yes
Dutpatient Visit?	Yes
Reported Complaint To?	Other
Need Additional/ e FDA Contact?	Unknown

#### Remarks

Consumer states that she continues to experience respiratory difficulty and is scheduled for a pulmonary function test next month. Consumer has a history of asthma for 25 years and currently utilizes a rescue inhaler. Also has a history of gastric bypass surgery ten years prior. In addition to the FDA, the consumer has contacted the retail establishment, the corporate headquarters of the retail establishment, OSHA, Clinton County Health Department and Albany County Health Department.

Complaint Symptoms			
Symptom Name	Duration	Remarks	
Coughing	null null	Blood in Sputum	

Health Care Type	Provider Name	Address	Phone	Occupation Stay Dates
Health Care Professional	(b) (4)	(b) (4)	(b) (4)	
Hospital	(b) (4)	(b) (4)	(b) (4)	10/22/2013 - 10/26/2013
Emergency Room	(b) (4)	(b) (4)	(b) (4)	10/21/2013

Product and Labo	eling the second se
Brand Name	ion
Product Name	Keratin Smoothing Treatment

000001

FDA Product Code	53ED03	Qty/Unit	12 Fluid ounces	
UPC Code		Package	Bottle	
Exp/Use By Date		Lot/Serial		
Product Used?	Yes	Purchase Date	07/01/2013	
Date Used?	10/15/2013	Amount Consumed/Used	8 fl. oz.	
Amount Remained	4 fl. oz.	Date Discontinued	10/15/2013	
Country of Origin	United States	Imported Product?	No	
Retailer Name	Sally Beauty Supply	Label Remarks		
		Consumer states that there were no Lot numbers, UPC codes or expiration dates on product		

Manufacturer/Distributor					
FEI	Name & Address	Home District	Firm Type		
3003714912	Sally Beauty Supply LLC 3001 Colorado Blvd Denton TX 76210-6802	DAL-DO	Distributor		
1280090	Zoto's International, Inc. 100 Tokeneke Rd Darien CT 06820-4825	NWE-DO	Corporate Headquarters		

Initial Evaluation / Initial Disposition					
Initial Evaluation	FDA Action Indicated	Initial Disposition	Surveillance Info for Next El		
Disposition Date	03/31/2014				
Remarks					
DAL-DO CCC determined mfi	r is Zoto's Darien, CT. NWE-DO calle	d Zoto's Corporate office in Dari	en 203-655-8911 and left message for the		
manager in charge of the customer & salon section. Return phone call was never received. CC closed as surveillance info.					
Probl	em Keyword	Prob	lem Keyword Details		
Reaction		respiratory distress			

Cosmetic			
Cosmetic ID #25167			
DOB		Age	
Gender		Race	
Application Place	Salon/SPA	Reason for Use	Hair Preparations (Non-Coloring)
Application Site	Hair	Other Products?	
Directions			
Directions Followed?	Yes	Product Duration	
Frequency of Use	Every other month	Reaction Site	Other
Product Use in Off-Label Manner?	No	Off-Label Manner Desc	
Warning Statement on Label?		Warning Statements?	
Preexisting Conditions?	Yes	Treatment	Physician
Current Status	Unchanged		
Medical Diagnosis		Medical Treatment	

### Remarks

Reaction occured in the hair dresser applying the product to a client. The hair dresser complains of respiratory difficulty and a productive bloody cough requiring hospitalization.

#### Adverse Events

There is no adverse event information listed for this consumer complaint report.

[Close]

Zoto'S International, Inc. 100 Tokeneke Rd Darien, Connecticut 06820-4825

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