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 # 199772.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

Internet Consumer Report Form Approved: OMB No. 0910-0291, Expires: 09/30/2018 See PRA statement on reverse.

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

	FDA USE ONLY	Ī
Triage unit sequence #	672866	Ī
FDA Rec.		

MEDWATO	H
The FDA Safety Information Adverse Event Reporting	

Note: For date prompts of	"dd.mmm.vaaa" nlood	a ilea 2 diale	day 3 latter m	onth	3. D	lose or Amount	Frequency	Route		
abbreviation, and 4-digit y			uay, 3-letter in	ionar	#1	osc of Amount		Applied	to a surface, usually	
A. PATIENT INFO		GI ZU IV.			#1			the ski	n	
1. Patient Identifier 2. A		Month(s)	3. Sex	4. Weight						
(6) (6)	☐ Week(s)	Day(s)	Female	130	#2					
or E	Date of Birth (e.g., 08)	Feb 1925)	☐ Male	✓ lb		es of Use (From/T e duration, or best of 5-Aug-2016 - 05-A	o for each) (If unknowstimate) (dd-mmm		nt Abated After Use ped or Dose Reduced?	
5.a.Ethnicity (Check single best answer)	5.b.Race (Check all	that apply)			#2	Aug-2010 - 03-2	uy-2010	#1 🗌	Yes ✓ No Doesn apply	
	Asian A	merican India	n or Alaskan N	lative	5. Diagnosis or Reason for Use (indication)			#2	Yes No Doesn'	
Hispanic/Latino Black or African American White Not Hispanic/Latino Native Hawaiian or Other Pacific Islander						#1 smoothing hair treatment			10.Event Reappeared After Reintroduction?	
B. ADVERSE EVEN	I Native Hawaiia		acmc Islander		#2			9238	Yes ☐ No ☑ Doesn'	
1. Check all that apply				6. Is ti	ne Product	7. Is the Produc	#2 T	Yes No Doesn'		
✓ Adverse Event Product Problem (e.g., defects/malfunctions)				npounded?	Over-the-Cou	nter?	apply Lapply			
Product Use Error	Problem with Diff	erent Manuf	acturer of San	ne Medicine	-		#1 🗸 Yes	□ No		
2. Outcome Attributed	o Adverse Event (Ch	eck all that a	pply)		#2		#2 Yes	No	L	
Death Include date						ration Date (dd-mi			#2	
Life-threatening Hospitalization - Initi Other Serious (Impo	al or prolonged [Congenita	or Permanent I	Defects	1. Bra	nd Name	ICAL DEVICE		100	
3. Date of Event (dd-mm	A THOUGHT CALL STORY	-3100 Pd - 45-31	Report (dd-mn	26.00	2. Con	nmon Device Nam	ie		2b. Procode	
05-Aug-2016		6-Aug-201			3. Man	ufacturer Name, (City and State		AUG - 8 2011	
5. Describe Event, Prob See additional p			ıt.		4. Mod	del#	Lot#		5. Operator of Device	
									Health Professiona	
6. Relevant Tests/Labora See additional pa	and the second s				Catalo	og#	Expiration D	ate (dd-mmm-yyy	Lay User/Patient	
see additional pa	ige(a) for comp	Tere can			Seria	al #	Unique Iden	tifier (UDI) #	- Other	
7. Other Relevant Histor allergies, pregnancy, sa	y, Including Preexist moking and alcohol us	ng Medical e, liver/kidne	Conditions (e. y problems, etc.	g., :.)	6 If Im	planted, Give Dat	e (dd mmm social	7 If Explanted	Give Date (do-mmm-yyyy	
See additional pa	ge(s) for comp	lete text					11.61	, a Lapanisa,	51X 5 2415 (45 11111111))))	
					repr	nis a single-use de rocessed and reus	sed on a patient?	Yes	☐ No	
C. PRODUCT AVAIL 2. Product Available for		end product	to FDA)		9. If Ye	es to Item 8, Enter h	lame and Address	of Reprocessor		
☐ Yes ☑ No	Returned to Manuf	acturer on:	(dd-mmm-y	(7)(7)	F. C	THER (CONC	OMITANT) ME	DICAL PROD	UCTS	
D. SUSPECT PRO			Lane C		Produ	ct names and the	rapy dates (Excludes (s) for comple	e treatment of eve		
1. Name, Manufacturer/C #1 - Name and Strength	ompounder, Strengt		(uct label) # or Unique II	0		The state of the s	ee confidentiality		ok)	
Cezanne Perfect F	innish Keratin				1 Nan	ne and Address			70V	
TIV					Addre	ss (b) (6)		First Name (b) (6)		
#1 - Manufacturer/Compo	under	#1- Lot #			()	0) (6)	767	1-10-11-10-10-1	16) (6)	
Cezanne	MING	W. I. CO. W.			City () (0)	St	ate/Province/Region	20, 10, 10,	
#2 - Name and Strength		#2 - NDC	# or Unique ID	Y	Count	1000		ZIP/Postal (code (b) (6)	
- Hame and Suength		WZ - NUC	- or Orndre ID		Phone	#	E-mail			
					100000	Ith Professional? Yes \[\] No	3. Occupation	1	Also Reported to:	
#2 - Manufacturer/Compo	under	#2- Lot #					our identity disclo		Compounder User Facility	
				to ti	he manufacturer,	please mark this b	ox: ☑	Distributor/Importer		

B.5. Describe Event or Problem (continued)

At the end of a 3 hour hair treatment at a salon, I started having headaches, earaches, burning eyes. The headaches have persisted and worsened for the past 36 hours. As I am reporting this, I still have severe headaches, my eyes sting, my ears hurt. Earlier in the day, when I tried to exercise, I felt some chest burning, minimal. That symptom has subsided. The hair process was for Cezanne Perfect Finish Keratin Smoothing treatment. All I want to do is sleep or lie down. I can't go to work or engage in social activities. It has only been about 36 hours.

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

none

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

Medical Conditions: none

Allergies: none

Important Information: healthy, no medications

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

RX Meds: none

OTC Meds: sometimes Tums, vitamin D, ibuprofen

Internet Consumer Report Form Approved: OMB No. 0910-0291, Expires: 09/30/2018 See PRA statement on reverse.

CERTIFICATION S

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

	FDA USE ONLY
Triage unit sequence #	672866
FDA Rec. Date	

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

abbreviation and Au	digit year; for example		uay, a-letter in	ionui	II I	JUSE OF AIRO	1	equency		to a surface, usua
A. PATIENT IN		, 01-Jul-2015.			#1				the skin	
1. Patient Identifier		s) Month(s)	3. Sex	4. Weight						
a) (6)	47 Week		Treez .	130	#2					
- Total	or Date of Birth (e.		▼ Female	√ lb						
	S. Pott Si biitii [6,	94 201 00 1262/	Male		Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)			Abated After Use ped or Dose Reduce		
In Confidence 5.a.Ethnicity (Chec	de Terre	to - William count to	100	☐ kg	#1 05-Aug-2016 - 05-Aug-2016				Ves INO IDO	
single best answer)		eck all that apply)			#2				арру	
Hispanic/Latino Asian American Indian or Alaskan Native					Diagnosis or Reason for Use (indication) smoothing hair treatment			#2 L Y	#2 Yes No apply	
☐ Black or African American ☑ White					#1			10.Even	10.Event Reappeared After Reintroduction?	
✓ Not Hispanic/Latino Native Hawaiian or Other Pacific Islander				#2			9 23815	#1 Yes No Does		
	VENT, PRODUC	TPROBLEM			#2					app
1. Check all that a					100000	he Product		s the Product	#2 1	res No Do
Adverse Event		blem (e.g., defect			- F	mpounded?		Over-the-Counter?	lo	
Product Use E	rror Problem wit	h Different Manuf	acturer of San	ne Medicine	-					
2. Outcome Attribu	ited to Adverse Eve	nt (Check all that a	ipply)		#2 B Exp	Yes iration Date (2,978	The state of the s	10	45
Death Include	date (dd-mmm-yyyy)							L DEVICE		#2
Life-threatening Hospitalization		☐ Disability	or Permanent [al Anomaly/Birth	-		and Name	MEDICA	E DEVICE		
Required Inter	vention to Prevent Pe	rmanent Impairme	nt/Damage (De	vices)	2. Cor	mmon Device	Name			2b. Procode TU
3. Date of Event (d	d-mmm-yyyy)	4. Date of this	Report (dd-mn	пт-уууу)	0.11			and State		Alte
05-Aug-2016		06-Aug-20	16		3. Mar	nufacturer Na	ame, City a	ind State		AUG - 8 2
. Describe Event,	Problem or Product	Use Error								
See additiona	1 page(s) for	complete tex	ĸt.		4. Mo	del#		Lot#		5. Operator of Dev
										Health Professi
N. L.					Catal	og#		Expiration Date (d	d-mmm. vacas	
	aboratory Data, Incl	and the second s						Expiration Date (0	и-пппп-уууу	
ee additiona	l page(s) for	complete tex	L.							Other:
					Seria	al#		Unique Identifier	(UDI) #	
Other Relevant L	istory, Including Pre	evisting Medical	Conditions (a	0	-					L.
allergies, pregnan	cy, smoking and alco	hol use, liver/kidne	y problems, etc	5)	E IF In	nplanted, Giv	o Date (de	mmm sound 7 H	Explanted G	live Date (do-mmm-y
ee additional	page(s) for	complete tex	t.		U. II III	inplanted, GIV	a Date (do	-шш-уууу)	- parisu, u	a value (a c-minute)
					8. Is t	his a single-u	use device	that was	☐ Yes [□ No
PROPUET	VALLABILITY						A Company of the St.			_ No
Product Available	VAILABILITY e for Evaluation?(Do	not send product	to EDA)		9. 11 4	es to item 8, E	nter Name	and Address of Rep	rocessor	
Yes N		Manufacturer on:								
		wanulacturer on:	(dd-mmm-y	(УУУ)				TANT) MEDICA		
D. SUSPECT F			200.1		Produ	ict names an	d therapy	dates (Exclude trea	tment of ever	
Name, Manufactu 1 - Name and Stren	rer/Compounder, St		duct label) C# or Unique II	0		THE STATE OF STREET		onfidentiality sect		(c)
	t Finnish Ker				1. Nar	ne and Addre	ess	The second secon		
	N.	-			Last N	Name (b) (6)		First I	Name: (b) (6	
	()				Addre	155				
1 - Manufacturer/Co	ompounder	#1- Lot #			City (b	0) (6)		State/Dr	ovince/Regio	n (b) (6)
ezanne					l Suy	4.4.7		State/Pi	- vincersayiu	
		We 110.0			Count	ry: us			ZIP/Postal C	ode (b) (6)
2 - Name and Stren	ngth	#2 - NDC	# or Unique ID		Phone	#:		E-mail:		
								(b) (6)		
					177	alth Professio	onal? 3. O	ccupation	14	Also Reported to:
2 - Manufacturer/Co	ompounder	#2- Lot #				Yes No				Manufacturer/
FE - Manufacture//Cl	unpounder	#2- LOT #			E 11	ou de Not	ant up us	landiby displayed		Compounder User Facility
					to t	he manufacti	urer, pleas	lentity disclosed e mark this box:		Distributor/Import
										1 of 2

B.5. Describe Event or Problem (continued)

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

none

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

Medical Conditions: none

Allergies: none

Important Information: healthy, no medications

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

RX Meds: none

OTC Meds: sometimes Tums, vitamin D, ibuprofen

CEZANNE PROFESSIONAL HAIR PRODUCTS 55 SE 2nd Avenue Delray Beach, Florida 33444

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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.

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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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

Department: CFSAN
CTU FDag 500 For06-Oct-2016

Total Pages: 4

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

Receipt No: RCT-7205

Basic Details					
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
FDA Received Date	06-Oct-2016	CTU Received Date	06-Oct-2016		
CTU Triage Date					
Report Type	Spontaneous	Report Classification			
Assign To	User				
User/Group					
Forward to Department	CDER				

Contact								
Source Form Type	First Name	Last Name	Email Address	Phone				
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)				

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Department: CFSAN

Receipt No: RCT-7205 CTU FDag 500 For 06-Oct-2016

What kind of problem was it?	Were hurt or had a bad side	e effect (including new or worsening	symptoms)					
(Check all that apply)	Used a product incorrectly	which could have or led to a problem						
	Noticed a problem with the							
	Had problems after switchi	ng from one product maker to anothe	er maker					
Did any of the following happen?	Hospitalization - admitted of	•						
(Check all that apply)	 	ermanent harm (for medical devices o	only)					
	Disability or health problen	Birth defect						
	Life-threatening							
	Death							
	Other serious/important me	edical incident						
Date of Death								
Date the problem occurred	13-Jul-2016							
Tell us what happened and how it	happened (Include as r	nany details as possible)						
**	* * *	<u> </u>	bness/tingling feeling on my face and flu					
like symptoms with nausea and diarr	hea. I contacted my hairdress	ser and she had never heard of s	such symptoms. After 1 week of dealing					
			ntacted the company and was able to get as on July 23, 2016. I continued having					
symptoms and they progressed over								
			summary of Dr's appointment's to date					
List any relevant tests or laborato	rv data if vou know the	m (Include dates)						
	J	(
Section B - About the Products			1 of 1					
Name of the product as it appears	BRAZILIAN BLOWOUT	AÇAI PROFESSIO						
on the box, bottle, or package (Include as many names as you								
see)								
Name of the company that makes	Brazilian Blowout							
(or compounds) the product Is the Product Compounded?	Yes							
(Your health professional may be	103							
able to help you identify whether								
the drug was compounded.) Is the Product Over-the-Counter?								
		Is the Product Over-the-Counter?						
Expiration date								
Expiration date Lot number								
Lot number NDC number								
Lot number NDC number		If Other						
Lot number		If Other						
Lot number NDC number Strength (for example, 250 mg per		If Other						
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency		If Other If Other						
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used	Other	If Other	hair					
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started taking or using the product		If Other If Other	hair					
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started		If Other If Other	hair					
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started taking or using the product Date the person stopped taking or		If Other If Other	hair					

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Department: CFSAN CTU FDAQ350031 For06-Oct-2016

Receipt No: RCT-7205	CTU FDAG5500AF0r06-Oct-2016				
product?	Total Pages: 4				
Did the problem return if the person started taking or using the product again?					
Do you still have the product in case we need to evaluate it?	No				
Why was the person using the pro	duct? (such as what condition was it supposed to treat)				
Section C - About the Medical Dev	vice				
Name of medical device					
Name of the company that makes the medical device					
Model #					
Catalog #					
Serial #					
Lot #					
Unique Identifier (UDI) #					
Expiry Date					
Was someone operating the medical device when the problem occurred?					
For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)					
For implanted medical devices ON	LY (such as pacemakers, breast implants, etc.)				
For implanted medical devices ON Date the implant was put in	Date the implant was taken out (If relevant)				
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If				
Date the implant was put in	Date the implant was taken out (If relevant)				
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If relevant)				
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If relevant)				
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Date the implant was put in Other identifying information (Th	Date the implant was taken out (If relevant)				
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate				
Other identifying information (Th	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate				
Date the implant was put in Other identifying information (The them) Section D - About the Person Who	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem				
Other identifying information (Them) Section D - About the Person Who	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem				
Other identifying information (The them) Section D - About the Person Who Person's Initials Sex	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem				
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant)				
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Dit D				
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Bir B				
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Date the implant was taken out (If relevant) Had the expiration date, if you can locate				
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Bir B				
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Since Female				
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Output				
Other identifying information (Them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Choose all that apply)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Output				
Other identifying information (Them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Choose all that apply)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem				

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Department: CFSAN
CTU FPAGS OBT FOR OCT-2016

Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. neurontin List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. zyrtec OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1 **Product Name** If Other Strength **Therapy Start Date** Therapy End Date Section E - About the Person Filling Out This Form (b) (6) Last name First name (b)(6)Number/Street (b)(6)City (b)(6)(b) (6) State/Province USA Country (b)(6)ZIP or Postal code Telephone number (b)(6)**Email address** (b) (6) Today's date 06-Oct-2016 Did you report this problem to the Yes company that makes the product (the manufacturer/compounder)? If you do NOT want your identity disclosed to the manufacturer, place an X in this box:

Receipt No: RCT-7205

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Department: CFSAN
CTU FDag 500 For06-Oct-2016

Total Pages: 4

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

Receipt No: RCT-7205

Basic Details					
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
FDA Received Date	06-Oct-2016	CTU Received Date	06-Oct-2016		
CTU Triage Date					
Report Type	Spontaneous	Report Classification			
Assign To	User				
User/Group					
Forward to Department	CDER				

Contact								
Source Form Type	First Name	Last Name	Email Address	Phone				
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)				

Generated by: system Generated on: 06-Oct-2016 11:15:53 Page 1 of 4

Department: CFSAN

Receipt No: RCT-7205 CTU FDag 500 For 06-Oct-2016

What kind of problem was it?	Were hurt or had a bad side	e effect (including new or worsening	symptoms)
(Check all that apply)	Used a product incorrectly	which could have or led to a problem	
	Noticed a problem with the		
	Had problems after switchi	ng from one product maker to anothe	er maker
Did any of the following happen?	Hospitalization - admitted of	•	
(Check all that apply)	 	ermanent harm (for medical devices o	only)
	Disability or health problen Birth defect	n	
	Life-threatening		
	Death		
	Other serious/important me	edical incident	
Date of Death			
Date the problem occurred	13-Jul-2016		
Tell us what happened and how it	happened (Include as r	nany details as possible)	
**	* * *	<u> </u>	bness/tingling feeling on my face and flu
like symptoms with nausea and diarr	hea. I contacted my hairdress	ser and she had never heard of s	such symptoms. After 1 week of dealing
			ntacted the company and was able to get as on July 23, 2016. I continued having
symptoms and they progressed over			
			summary of Dr's appointment's to date
List any relevant tests or laborato	rv data if vou know the	m (Include dates)	
	J	(
Section B - About the Products			1 of 1
Name of the product as it appears	BRAZILIAN BLOWOUT	AÇAI PROFESSIO	
on the box, bottle, or package (Include as many names as you			
see)			
Name of the company that makes	Brazilian Blowout		
(or compounds) the product Is the Product Compounded?	Yes		
(Your health professional may be	103		
able to help you identify whether			
the drug was compounded.) Is the Product Over-the-Counter?			
Expiration date			
Expiration date Lot number			
Lot number NDC number			
Lot number NDC number		If Other	
Lot number		If Other	
Lot number NDC number Strength (for example, 250 mg per		If Other	
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency		If Other If Other	
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used	Other	If Other	hair
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started taking or using the product		If Other If Other	hair
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started		If Other If Other	hair
Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started taking or using the product Date the person stopped taking or		If Other If Other	hair

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Department: CFSAN CTU FDAQ350031 For06-Oct-2016

Receipt No: RCT-7205	CTU FDAG5500AF0r06-Oct-2016
product?	Total Pages: 4
Did the problem return if the person started taking or using the product again?	
Do you still have the product in case we need to evaluate it?	No
Why was the person using the pro	duct? (such as what condition was it supposed to treat)
Section C - About the Medical Dev	vice
Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	
For implanted medical devices ON	LY (such as pacemakers, breast implants, etc.)
For implanted medical devices ON Date the implant was put in	Date the implant was taken out (If relevant)
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If
Date the implant was put in	Date the implant was taken out (If relevant)
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If relevant)
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If relevant)
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If relevant)
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If relevant)
Date the implant was put in Other identifying information (Th	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate
Other identifying information (Th	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate
Date the implant was put in Other identifying information (The them) Section D - About the Person Who	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem
Other identifying information (Them) Section D - About the Person Who	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem
Other identifying information (The them) Section D - About the Person Who Person's Initials Sex	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant) Date the implant was taken out (If relevant) Had the Problem Date the implant was taken out (If relevant)
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Dit D
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Bir B
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Date the implant was taken out (If relevant) Had the expiration date, if you can locate
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Bir B
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Since Female
Date the implant was put in Other identifying information (The them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Output
Other identifying information (Them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Choose all that apply)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem Output
Other identifying information (Them) Section D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Choose all that apply)	Date the implant was taken out (If relevant) e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Had the Problem

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Department: CFSAN
CTU FPAGS OBT FOR OCT-2016

Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. neurontin List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. zyrtec OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1 **Product Name** If Other Strength **Therapy Start Date** Therapy End Date Section E - About the Person Filling Out This Form (b) (6) Last name First name (b)(6)Number/Street (b)(6)City (b)(6)(b) (6) State/Province USA Country (b)(6)ZIP or Postal code Telephone number (b)(6)**Email address** (b) (6) Today's date 06-Oct-2016 Did you report this problem to the Yes company that makes the product (the manufacturer/compounder)? If you do NOT want your identity disclosed to the manufacturer, place an X in this box:

Receipt No: RCT-7205

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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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 202704.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

203353

CTU No.: FDA-CDER-CTU-9271
Department: CFSAN
CTU FDAgs GRE Fortal-Oct-2016
Total Pages: 5

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

Receipt No: RCT-10349

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	23-Oct-2016	CTU Received Date	23-Oct-2016
CTU Triage Date			
Report Type	Spontaneous	Report Classification	
Assign To	User	*	
User/Group			
Forward to Department	CDER		

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

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Department: CFSAN CTU FRAGE OR FORM-Oct-2016

Receipt No: RCT-10349

Section A - About the Problem

What kind of problem was it?

Were hurt or had a bad side effect (including new or worsening)

What kind of problem was it? (Check all that apply)	Used a product inco	bad side effect (including new or worse orrectly which could have or led to a pro with the quality of the product switching from one product maker to a	oblem	
Did any of the following happen? (Check all that apply)	Hospitalization - ad Required help to proposed by Disability or health Birth defect Life-threasening	mitted or stayed longer event permanent harm (for medical de		
Date of Death				
Other serious/important medical incident				
Date the problem occurred	23-Oct-2016			
us what happened and how it	hannoned (Indeed	o no manu dataile as assalla	le)	
any relevant tests or laborator	ry data if you kno	w them (Include dates)		
any relevant tests or laborato	ry data if you kno	w them (Include dates)		
	ry data if you kno	w them (Include dates)		1 of 1
ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you	ry data if you kno	w them (Include dates)		1 of 1
any relevant tests or laborator ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product		w them (Include dates)		1 of 1
iou B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether		w them (Include dates)		1 of 1
ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		w them (Include dates)		1 of 1
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ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date		w them (Include dates)		1 of 1
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ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g)				1 0f 1
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Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency		If Other If Other		1 of 1
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Department: CFSAN CTU FDag 500 For 24-Oct-2016

Receipt No: RCT-10349	CTU FDag35@HEDra4-Oct-2016
person reduced the dose or stopped taking or using the product?	Total Pages: 5
Did the problem return if the person started taking or using the product again?	
Do you still have the product in case we need to evaluate it?	No
Why was the person using the pro	duct? (such as what condition was it supposed to treat)
Keratin treatment in a hair salon	
Section C - About the Medical Dev	vice
Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the	
medical device when the problem occurred?	
For implanted medical devices ON	LY (such as pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If
	relevant)
Other identifying information (Th	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate
Section D - About the Person Who	Had the Problem
Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	41 Year(s)
Date of Birth	
Weight	91.35 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander
	Native Hawaiian or Other Pacific Islander
	White
	Black or African American

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

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Department: CFSAN CTU FDags Date or 24-Oct-2016

	Diabetes and high blood pressure	Total Pages: 5
Ple	ase list all allergies (such as to c	rugs, foods, pollen or others)
	Eggs, Bactrim, sulfa drugs, rocephrin	
Lis	t any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)
		8, F - 8 , · · · · · · · · · · · · · · · ·
T is	t all aurrant preserintian madia	ations and medical devices being used.
		ations and medical devices being used.
	Metforim, losartan	
Lis	t all over-the-counter medication	ns and any vitamins, minerals, supplements, and herbal remedies being used.
ОТ	THER (CONCOMITANT) MEI	OICAL PRODUCTS 1 of 1
U		TCAL I RODUCTS
	Product Name	TC OIL
	Strength	If Other
	Therapy Start Date	
	Therapy End Date	
Sec	ction E - About the Person Fillir	a Out This Form
	Last name	(b) (6)
	First name	(b) (6)
	Number/Street	
		(b) (6)
	City State/Province	(b) (6)
		TICA
	Country ZIP or Postal code	USA (b) (6)
	Telephone number Email address	(b) (6) (b) (c)
	Linan audi CSS	(5) (6)
		22 Oct 2016
	Today's date	23-Oct-2016
	Today's date Did you report this problem to the	23-Oct-2016 No
	Today's date	

Receipt No: RCT-10349

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Department: CFSAN

CTU FDag 500 For 24-Oct-2016

disclosed to the manufacturer,	Total Pages: 5	
place an X in this box:		

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Department: CFSAN
CTU FDag 500 For 24-Oct-2016

Total Pages: 5

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

Receipt No: RCT-10349

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	•	
FDA Received Date	23-Oct-2016	CTU Received Date	23-Oct-2016
CTU Triage Date		•	
Report Type	Spontaneous	Report Classification	
Assign To	User	•	
User/Group			
Forward to Department	CDER		

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)

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Receipt No: RCT-10349

Department: CFSAN
CTU FDAGSOUS ForD4-Oct-2016
Total Parameters

Sec	tion A - About the Problem	
	What kind of problem was it?	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
		Noticed a problem with the quality of the product
		Had problems after switching from one product maker to another maker
İ	Did any of the following happen?	Hospitalization - admitted or stayed longer
	(Check all that apply)	Required help to prevent permanent harm (for medical devices only)
		Disability or health problem
		Birth defect
		Life-threatening
		Death
		Other serious/important medical incident
f	Date of Death	
İ	Other serious/important medical	
	incident	
	Date the problem occurred	23-Oct-2016
Tel	l us what happened and how it	happened (Include as many details as possible)
	I received a keratin treatment and exp	perienced coughing, watering of the eyes and burning of the nose and throat.
L		
Lis	t any relevant tests or laborato	ry data if you know them (Include dates)
	j 1010 ; 0010 01 111 01 111 01	y and it you must diem (member ands)
Sec	tion B - About the Products	1 of 1
Sec	tion B - About the Products	
Sec	Name of the product as it appears on the box, bottle, or package	1 of 1 Keratin
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you	
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes	
Secc	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product	
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be	
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether	
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter?	
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Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number	Keratin
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per	
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g)	Keratin If Other
Seco	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity	Keratin If Other If Other
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency	Keratin If Other If Other If Other If Other
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used	Keratin If Other If Other If Other If Other If Other If Other
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started	Keratin If Other If Other If Other If Other
Seco	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started taking or using the product	Keratin If Other If Other If Other If Other If Other If Other
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started	Keratin If Other If Other If Other If Other If Other If Other

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Department: CFSAN CTU FDag 500 For 24-Oct-2016

Receipt No: RCT-10349	CTU FDag8500st Form4-Oct-2016
person reduced the dose or stopped taking or using the product?	Total Pages: 5
Did the problem return if the person started taking or using the product again?	
Do you still have the product in case we need to evaluate it?	No
Why was the person using the pro	duct? (such as what condition was it supposed to treat)
Keratin treatment in a hair salon	
Section C - About the Medical Dev	rice
Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	
For implanted medical devices ON	LY (such as pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If
The same same same same same same same sam	relevant)
Other identifying information (Th	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate
Section D - About the Person Who	Had the Problem
Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	41 Year(s)
Date of Birth	
Weight	91.35 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino American Indian or Alaskan Native
Race (Choose all that apply)	American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander
	Asian
	White
	Black or African American

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

Generated by: system Generated on: 23-Oct-2016 00:45:46 Page 3 of 5

Department: CFSAN
CTU FDag 500 Form - Oct-2016

	Diabetes and high blood pressure	Total Pages: 5
	3	
DI		
Ple	ase list all allergies (such as to d	
	Eggs, Bactrim, sulfa drugs, rocephrin	
Lis	t any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)
	· · ·	
Lis		ations and medical devices being used.
	Metforim, losartan	
Lis	t all over-the-counter medicatio	ns and any vitamins, minerals, supplements, and herbal remedies being used.
ПО	HER (CONCOMITANT) MED	NICAL PRODUCTS
OT	THER (CONCOMITANT) MED	DICAL PRODUCTS 1 of 1
OT	Product Name	
ΓΟ	Product Name Strength	DICAL PRODUCTS 1 of 1 If Other
TO	Product Name Strength Therapy Start Date	
OT	Product Name Strength	
	Product Name Strength Therapy Start Date Therapy End Date	If Other
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin	g Out This Form
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name	g Out This Form (b) (6)
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin	If Other
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name	g Out This Form (b) (6)
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name First name	If Other
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name First name Number/Street	If Other
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name First name Number/Street City	If Other
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name First name Number/Street City State/Province	If Other
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name First name Number/Street City State/Province Country	If Other
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name First name Number/Street City State/Province Country ZIP or Postal code	If Other
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address	If Other
	Product Name Strength Therapy Start Date Therapy End Date tion E - About the Person Fillin Last name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address Today's date	If Other
	Product Name Strength Therapy Start Date Therapy End Date Ition E - About the Person Fillin Last name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address Today's date Did you report this problem to the company that makes the product	If Other
	Product Name Strength Therapy Start Date Therapy End Date Ition E - About the Person Fillin Last name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address Today's date Did you report this problem to the	If Other

Receipt No: RCT-10349

Generated by: system Generated on: 23-Oct-2016 00:45:46 Page 4 of 5

Department: CFSAN

CTU FDag3500R For24-Oct-2016

disclosed to the manufacturer,	Total Pages: 5	
place an X in this box:		

Receipt No: RCT-10349

Generated by: system Generated on: 23-Oct-2016 00:45:46 Page 5 of 5

Department: CFSAN
CTU TROGES 5000 FORM Nov-2016

Total Pages: 5

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

Receipt No: RCT-15824

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	20-Nov-2016	CTU Received Date	20-Nov-2016
CTU Triage Date			
Report Type	Spontaneous	Report Classification	
Assign To	User		
User/Group			
Forward to Department	CDER		

Contact	Contact				
Source Form Type	First Name	Last Name	Email Address	Phone	
	(b) (6)	(b) (6)	(b) (6)		

Generated by: system Generated on: 20-Nov-2016 19:45:37 Page 1 of 5

Department: CFSAN Receipt No: RCT-15824 CTU TROGES 5000 FOR IN NOV-2016 Section A - About the Problem

Section A - About the I Toblem			
What kind of problem was it?	Were hurt or had a bad side	effect (including new or worsening	symptoms)
(Check all that apply)	Used a product incorrectly w	hich could have or led to a probler	n
	Noticed a problem with the q	quality of the product	
	Had problems after switchin	g from one product maker to anoth	ner maker
Did any of the following happen?	Hospitalization - admitted or	stayed longer	
(Check all that apply)	Required help to prevent per	manent harm (for medical devices	only)
	Disability or health problem		
	Birth defect		
	Life-threatening		
	Death		
	Other serious/important med	lical incident	
Date of Death	<u>V</u>		
Other serious/important medical	Drowsiness, sinus irritation		
incident	Diowsiness, sinus irritation		
Date the problem occurred	20-Nov-2016		
Tell us what happened and how it	happened (Include as m	any details as possible)	
I was having my hair cut at a salon w	here another customer was ha	ving a Brazilian blow out in	the next chair, and I was exposed to the
		after I left the salon. The adve	erse effects I experienced included sinus
irritation, tiredness, headache and diz	zziness.		
I ist any volument tooks on labourts	da4a :f l a 4b a	· (Include detect	
List any relevant tests or laborato	ry data ii you know then	n (Include dates)	
None			
Section B - About the Products			1 of 1
Name of the product as it appears	Brazilian blowout		
on the box, bottle, or package (Include as many names as you			
see)			
Name of the company that makes	GIB, LLC		
(or compounds) the product			
Is the Product Compounded?			
(Your health professional may be able to help you identify whether			
the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per	 	If Other	
500 ml or 1g)		II Other	
Quantity		If Other	
Frequency	Other	If Other	Once
	Topical	If Other	
How was it taken or used		II Ouici	
	<u> </u>	II Other	
How was it taken or used Date the person first started taking or using the product	20-Nov-2016	II Other	l
Date the person first started	<u> </u>	11 Oute	

Generated by: system 20-Nov-2016 19:45:37 Page 2 of 5 Generated on:

Department: CFSAN CTU TROAS SUPE FOR IN NOV-2016

Receipt No: RCT-15824	CTU TRAGES 500 P. FORM Nov-2016		
person reduced the dose or stopped taking or using the product?	Total Pages: 5		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		
Do you still have the product in case we need to evaluate it?	No		
Why was the person using the pro	duct? (such as what condition was it supposed to treat)		
Treatment for straightening hair in a	salon		
Section C - About the Medical Dev	rice		
Name of medical device			
Name of the company that makes the medical device			
Model #			
Catalog #			
Serial #			
Lot #			
Unique Identifier (UDI) #			
Expiry Date			
Was someone operating the medical device when the problem occurred?			
For implanted medical devices ON	LY (such as pacemakers, breast implants, etc.)		
Date the implant was put in	Date the implant was taken out (If relevant)		
Other identifying information (Th them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate		
Section D - About the Person Who	Had the Problem		
Person's Initials	SW		
Sex	Female		
Age (specify unit of time for age)	44 Year(s)		
Date of Birth	52.1 (/-)		
Weight Ethnicity (Chaosa only one)	53.1 kg(s)		
Ethnicity (Choose only one) Race (Choose all that apply)	Not Hispanic/Latino American Indian or Alaskan Native		
Nace (Choose an that apply)	Native Hawaiian or Other Pacific Islander		
	Asian		
	White		
	Black or African American		
List known medical conditions (Su	ch as diabetes, high blood pressure, cancer, heart disease, or others)		

Department: CFSAN
CTU TROGES SOUR FORM Nov-2016

	None, healthy	Total Pages: 5
Ple	ease list all allergies (such as to d	rugs, foods, pollen or others)
	None	
	Trone	
T ic	t any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)
ILIS	· ·	ton about the person (such as smoking, pregnancy, alcohol use, etc.)
	Heathy	
Lis		ations and medical devices being used.
	None	
Lis	st all over-the-counter medication	ns and any vitamins, minerals, supplements, and herbal remedies being used.
	Ibuprofen	
O.I	THER (CONCOMITANT) MED	DICAL PRODUCTS 1 of 1
	Product Name	
	Strength	If Other
	Therapy Start Date	
	Therapy End Date	
<u> </u>		O AMILL D
Sec	ction E - About the Person Fillin	
	Last name	(b) (6)
	First name	(b) (6)
	Number/Street	(b) (6)
	City	(b) (6)
	State/Province	(b) (6)
	Country	USA
	ZIP or Postal code	(b) (6)
	Telephone number	
	Email address	(b) (6)
	Today's date	20-Nov-2016
	Did you report this problem to the	No
	company that makes the product (the manufacturer/compounder)?	
	If you do NOT want your identity	

Receipt No: RCT-15824

Generated by: system Generated on: 20-Nov-2016 19:45:37 Page 4 of 5

Department: CFSAN

Receipt No: RCT-15824 CTU TROG 35000 Form Nov-2016

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

Generated by: system Generated on: 20-Nov-2016 19:45:37 Page 5 of 5

Department: CFSAN
CTU TROGES 5000 FORM Nov-2016

Total Pages: 5

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

Receipt No: RCT-15824

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	20-Nov-2016	CTU Received Date	20-Nov-2016
CTU Triage Date			
Report Type	Spontaneous	Report Classification	
Assign To	User		
User/Group			
Forward to Department	CDER		

Contact	Contact				
Source Form Type	First Name	Last Name	Email Address	Phone	
	(b) (6)	(b) (6)	(b) (6)		

Generated by: system Generated on: 20-Nov-2016 19:45:37 Page 1 of 5

Department: CFSAN Receipt No: RCT-15824 CTU TROGES 5000 FOR IN NOV-2016 Section A - About the Problem

Section A - About the I Toblem			
What kind of problem was it?	Were hurt or had a bad side	effect (including new or worsening	symptoms)
(Check all that apply)	Used a product incorrectly w	hich could have or led to a probler	n
	Noticed a problem with the q	quality of the product	
	Had problems after switchin	g from one product maker to anoth	ner maker
Did any of the following happen?	Hospitalization - admitted or	stayed longer	
(Check all that apply)	Required help to prevent per	manent harm (for medical devices	only)
	Disability or health problem		
	Birth defect		
	Life-threatening		
	Death		
	Other serious/important med	lical incident	
Date of Death	<u>V</u>		
Other serious/important medical	Drowsiness, sinus irritation		
incident	Diowsiness, sinus irritation		
Date the problem occurred	20-Nov-2016		
Tell us what happened and how it	happened (Include as m	any details as possible)	
I was having my hair cut at a salon w	here another customer was ha	ving a Brazilian blow out in	the next chair, and I was exposed to the
		after I left the salon. The adve	erse effects I experienced included sinus
irritation, tiredness, headache and diz	zziness.		
I ist any volument tooks on labourts	da4a :f l a 4b a	· (Include detect	
List any relevant tests or laborato	ry data ii you know then	n (Include dates)	
None			
			4 04
Section B - About the Products			1 of 1
Name of the product as it appears	Brazilian blowout		
on the box, bottle, or package (Include as many names as you			
see)			
Name of the company that makes	GIB, LLC		
(or compounds) the product			
Is the Product Compounded?			
(Your health professional may be able to help you identify whether			
the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per		If Other	
500 ml or 1g)		II Other	
Quantity		If Other	
Frequency	Other	If Other	Once
	Topical	If Other	
How was it taken or used		II Ouici	
	<u> </u>	II Other	
How was it taken or used Date the person first started taking or using the product	20-Nov-2016	II Other	l
Date the person first started	<u> </u>	11 Oute	

Generated by: system 20-Nov-2016 19:45:37 Page 2 of 5 Generated on:

Department: CFSAN CTU TROAS SUPE FOR IN NOV-2016

Receipt No: RCT-15824	CTU TRD96350016 F@mNov-2016
person reduced the dose or stopped taking or using the product?	Total Pages: 5
Did the problem return if the person started taking or using the product again?	Doesn't Apply
Do you still have the product in case we need to evaluate it?	No
Why was the person using the pro	duct? (such as what condition was it supposed to treat)
Treatment for straightening hair in a	salon
Section C - About the Medical Dev	rice
Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	
For implanted medical devices ON	LY (such as pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If relevant)
Other identifying information (Th them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate
Section D - About the Person Who	. Had the Problem
Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	44 Year(s)
Date of Birth	
Weight	53.1 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	American Indian or Alaskan Native
	Native Hawaiian or Other Pacific Islander
	Asian
	White
	Black or African American
List known medical conditions (Su	ich as diabetes, high blood pressure, cancer, heart disease, or others)

Department: CFSAN
CTU TROGES SOUR FORM Nov-2016

	None, healthy	Total Pages: 5
Ple	ease list all allergies (such as to d	rugs, foods, pollen or others)
	None	
	Trone	
T ic	t any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)
ILIS	· ·	ton about the person (such as smoking, pregnancy, alcohol use, etc.)
	Heathy	
Lis		ations and medical devices being used.
	None	
Lis	st all over-the-counter medication	ns and any vitamins, minerals, supplements, and herbal remedies being used.
	Ibuprofen	
O.I	THER (CONCOMITANT) MED	DICAL PRODUCTS 1 of 1
	Product Name	
	Strength	If Other
	Therapy Start Date	
	Therapy End Date	
<u> </u>		O AMILL D
Sec	ction E - About the Person Fillin	
	Last name	(b) (6)
	First name	(b) (6)
	Number/Street	(b) (6)
	City	(b) (6)
	State/Province	(b) (6)
	Country	USA
	ZIP or Postal code	(b) (6)
	Telephone number	
	Email address	(b) (6)
	Today's date	20-Nov-2016
	Did you report this problem to the	No
	company that makes the product (the manufacturer/compounder)?	
	If you do NOT want your identity	

Receipt No: RCT-15824

Generated by: system Generated on: 20-Nov-2016 19:45:37 Page 4 of 5

Department: CFSAN

Receipt No: RCT-15824 CTU TROG 35000 Form Nov-2016

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

Generated by: system Generated on: 20-Nov-2016 19:45:37 Page 5 of 5

GIB LLC 6855 Tujunga Ave. North Hollywood, California 91605

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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 204550.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

Non-serious Injuries/ Illness

10/31/2016

11/22/2016

Yes

No

No

FDA

[Close]

FACTS Interface

FACTS Complaint #147718 (CAERS #204959)

Complaint Date 11/22/2016 **Complaint Source** Consumer Accomplishing District NYK-DO **Complaint Status** Archived Phone Call

Source Phone

How Received

Complainant Identification

Name **Work Phone** (b) (6) Address **Home Phone** (b)(6)**Source POC Name**

City State

(b) (6) Zip

Province Country

US

Mail Code

Complaint / Injury

Complaint Description

28 year old female complainant with no known allergies and no medical conditions reported her experience after receiving Rejuvenol Keratin Treatment. It was not her first time receiving Notification Date this treatment and she has not has problems in past with this type of treatment. It was her first time receiving service from this salon. After receiving the treatment, the next day she experienced difficulty breathing, nose bleeding, burning and swollen eyes and rash at her face. Complainant believes there Outpatient Visit? is formaldehyde in the product the salon used on her. She visited doctor and was treated with a medicated cream however most of her symptoms persist.

Reported Complaint To? Need Additional/ FDA Contact?

Emergency Room/

Adverse Event Result

Required Hospitalization?

Imported Product?

Label Remarks

Attended Health Professional? Unknown

Adverse Event Date

Notify EIO/EMOPS?

Remarks

See below****Authorized to forward

Complaint Symptoms

Symptom Name Duration Remarks Burning null null Burning eyes Difficulty breathing null null

Local swelling null null Swollen eyes NEC - Identify in Remarks 1 Day(s) Nose bleed Rash null null rash at face

Health Care Professional

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

Product and Labeling

Brand Name Rejuvenol

Product Name Keratin Treatment

FDA Product Code 53EC03 Qty/Unit **UPC Code** UNK **Package** Exp/Use By Date Lot/Serial UNK UNK **Product Used?** No **Purchase Date** UNK Date Used? 10/30/2016 Amount Consumed/Used UNK **Amount Remained** UNK **Date Discontinued** 10/30/2016

Country of Origin

Retailer Name Neo Blow & Color Hair Salon

Manufacturer/Distributor

No

FEI Name & Address **Home District** Firm Type 3010098292 Rejuvenol Lab 130 Lincoln St Copiague NY 11726-1227 NYK-DO Distributor

Initial Evaluation / Initial Disposition

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

Disposition Date 12/06/2016

Remarks

www.rejuvenol.com ---- 12/6/16 to date no response.****Will be referred to DOH at Nassau for their follow up as deemed

necessary.

Problem Keyword Details Problem Keyword

Experienced difficulty breathing, nose bleed, rash at face, burning and Reaction

swelling of eyes

Cosmetic

Cosmetic ID #25564

DOB 28 Age Gender White Female Race

Application Place Salon/SPA Reason for Use Hair Preparations (Non-Coloring)

Other Products? **Application Site** Face

Directions

Directions Followed? Yes **Product Duration**

Other **Reaction Site** Face Frequency of Use **Off-Label Manner Desc** Product Use in Off-Label Manner? No

Warning Statement on Label? Warning Statements?

Preexisting Conditions? No **Treatment** Physician

Current Status Unchanged

Medical Diagnosis Medical Treatment

Unknown Cream

Remarks

Frequency is every six weeks

Adverse Events

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

[Close]

REJUVENOL LAB 130 Lincoln St Copiague, New York 11726-1227

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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 204959.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

PLEASE TYPE OR USE BLACK INK

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

Page 1 of 1

	Dec OND Statement on reverse.
	FDA USE ONLY
riage unit	206021

A. PATIENT INFORMATION		D. SUSPECT PR	ODUCT(S)	
Patient Identifier Age at Time of Even Date of Birth:	nt, or 3. Sex 4. Weight	A STATE OF THE PARTY OF THE PAR	nufacturer (from product la ng Conditioner Fa	
In confidence	Male or kg	#1 Hen Cleans	ng conditioner re	all belieb
B. ADVERSE EVENT, PRODUCT		#2		
Check all that apply:		2. Dose or Amount	Freque	ncy Route
1. Adverse Event Product Prob	lem (e.g., defects/malfunctions)	#1		
Product Use Error Problem with	Different Manufacturer of Same Medicine	#2		
2. Outcomes Attributed to Adverse Event				
(Check all that apply) Death:	Disability or Permanent Damage	 Dates of Use (If unit best estimate) 	nown, give duration) from/to	Stopped or Dose Reduced?
(mm/dd/yyyy) Life-threatening	Congenital Anomaly/Birth Defect	W1		#1 Yes No Doesn' Apply
Hospitalization - Initial or prolonged	Other Serious (Important Medical Events)	#2		#2 Yes No Doesn
Required Intervention to Prevent Perma		4. Diagnosis or Reason	n for Use (Indication)	8. Event Reappeared After
Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)	#1		Reintroduction?
3. Date of Event (milladayyyy)	01/06/2017	#2		#1 Yes No Doesn' Apply
5. Describe Event, Problem or Product Use		6. Lot #	7. Expiration Date	TO Dye Due Doesn'
		#1	#1	— Apply
Caller says she'd used Wen F		#2	#2	9. NDC # or Unique ID
three years ago and liked it again and experienced a diff		E. SUSPECT ME		
three weeks of use there was falling out in clumps. So m	much so that she began	1. Brand Name	EDICAL DEVICE	
collecting it in baggies. I weeks and she was suspicious	s that WEN was the cause of	2. Common Device Na	ime	
her hair loss as there had be life, health or medications. Gunthy-Renker and person on formulations were different	. She contacted phone told her the	3. Manufacturer Name	, City and State	
was produced for QVC, Gunthy or the international market. fraud. Whilst the informati	y-Renker, for sale Canada, . She believes this is	4. Model #	Lot#	5. Operator of Device Health Professional
all natural, the actual prod ingredients that are not. S	duct sold contains She contacted WEN who said	Catalog #	Expiration Da	te (mm/dd/yyyy) Lay User/Patient
they could not tell her the change formulas they have no ingredients are difficult to	record. She says the	Serial #	Other #	Other:
believes lead, parabens, or ingredient used in this prod	formaldehyde to be an	6. If Implanted, Give D	ate (mm/dd/yyyy) 7. I	If Explanted, Give Date (mm/dd/yyyy)
maximum profit. However, it product and it is deceptive hair stylist and has been for	The caller is a license	8. Is this a Single-use	Device that was Reproces	ssed and Reused on a Patient?
nair styrist and has been it	or many years.		Enter Name and Address	of Reprocessor
6. Relevant Tests/Laboratory Data, Including	g Dates			
The caller is a license hair many years. She is certain being used. She says Chaz I email offering to pay her \$2	an unsafe ingredient is Dean recently sent her an			
The unused portion of the pr testing.	roduct is available for		COMITANT) MEDIC herapy dates (exclude treat	
7. Other Relevant History, Including Preexis race, pregnancy, smoking and alcohol use, li	sting Medical Conditions (e.g., allergies, liver/kidney problems, etc.)	G. REPORTER 1. Name and Address (b) (6)	(See confidentiality	section on back)
		Phone #	Te.	mail
		(b) (6)	(b) (6)
C. PRODUCT AVAILABILITY		2. Health Professiona	ALCOHOLD SERVICE SERVICES	4. Also Reported to:
Product Available for Evaluation? (Do not se	end product to FDA)	Yes 7 No	Non-Healthcare Profe	
✓ Yes No Returned to Ma	anufacturer on:(mm/dd/yyyy)		your identity disclosed r, place an "X" in this box:	User Facility ☑ Distributor/Importer

WEN BY CHAZ DEAN INC. 6444 Fountain Ave Los Angeles, California 90028

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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 206021.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

Department: CFSAN
CTU Triage Date 00 Forth-2017

Total Pages: 4

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

Receipt No: RCT-29542

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	01-Feb-2017	CTU Received Date	01-Feb-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	
Assign To	User		
User/Group			
Forward to Department	CDER		

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Generated by: system Generated on: 01-Feb-2017 10:15:15 Page 1 of 4

Department: CFSAN Receipt No: RCT-29542 CTU Triage Date 00B Foetb-2017

Sec	tion A - About the Problem				
	What kind of problem was it?	Were hurt or had a bad sid	e effect (including new or wor	sening symptoms)]
	(Check all that apply)	Used a product incorrectly which could have or led to a problem			
		Noticed a problem with the quality of the product			
		Had problems after switchi	ng from one product maker to	another maker	
	Did any of the following happen?	Hospitalization - admitted of	or stayed longer		1
	(Check all that apply)	Required help to prevent po	ermanent harm (for medical d	evices only)	
		Disability or health problem	n		
		Birth defect			
		Life-threatening			
		Death			
		Other serious/important me	edical incident		
	Date of Death				┨
	Date the problem occurred	28-Jan-2017			+
					<u></u>
Tel	l us what happened and how it	happened (Include as r	nany details as possi	ole)	
	opening the back door 3/4 of the way the heating process. She was using th burn. I couldn't leave because I still h	through the initial blow dry e Brazilian Blow Out Origin ad clients. This resulted in p	ing and flat ironing. Whi all formula, not the Zero. rolonged exposure witho	to proper ventilation. Only bringing out a fan and e all the chemicals were being released through Immediately eyes and my nose were starting to at ventilation. By the time I left, I could tell that y have to start a steroid if the medication doesn't	
Lis	t any relevant tests or laborator	v data if you know the	m (Include dates)		
Sec	tion B - About the Products			1 of 1	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian BlowOut Acai Pr	rofessio		
	Name of the company that makes (or compounds) the product	Brazilian BlowOut			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				-
	Is the Product Over-the-Counter?				
	Expiration date				
	Lot number				
	NDC number				
	Strength (for example, 250 mg per 500 ml or 1g)	11.8 % percent	If Other		
	Quantity		If Other		1
	Frequency		If Other		1
	How was it taken or used	Other	If Other	Hair	1
	Date the person first started taking or using the product	28-Jan-2017	II other	Tivii	1
	Date the person stopped taking or using the product				
	Did the problem stop after the person reduced the dose or				

Generated by: system Generated on: 01-Feb-2017 10:15:15 Page 2 of 4

Department: CFSAN
TU Triage DAt3500B Form-2017

Receipt No: RCT-29542 CTU Triage Date 00B Feet 2017 Total Pages: 4 product? Did the problem return if the person started taking or using the product again? Do you still have the product in No case we need to evaluate it? Why was the person using the product? (such as what condition was it supposed to treat) Curly hair Section C - About the Medical Device Name of medical device Name of the company that makes the medical device Model # Catalog # Serial # Lot# Unique Identifier (UDI) # **Expiry Date** Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Section D - About the Person Who Had the Problem Person's Initials Female Age (specify unit of time for age) 38 Year(s) **Date of Birth** Weight Ethnicity (Choose only one) Not Hispanic/Latino Race (Choose all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Generated by: system **Generated on:** 01-Feb-2017 10:15:15 **Page 3 of 4**

Department: CFSAN CTU Triage Dat 500B Foetb-2017

Receipt No: RCT-29542	CTU Triage Date 500 Forth-2017
Please list all allergies (such as to d	lrugs, foods, pollen or others) Total Pages: 4
List any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)
	g, pg,
List all current prescription medic	ations and medical devices being used.
List all over-the-counter medication	ons and any vitamins, minerals, supplements, and herbal remedies being used.
OTHER (CONCOMITANT) MEI	DICAL PRODUCTS 1 of 1
	DICAL PRODUCTS 1 01 1
Product Name	
Strength	If Other
Therapy Start Date	
Therapy End Date	
Section E - About the Person Fillin	or Out This Form
	<u> </u>
Last name First name	(b) (6) (b) (6)
Number/Street	(b) (o)
City	
State/Province	(b) (6)
Country	USA
ZIP or Postal code	
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	01-Feb-2017
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, place an X in this box:	

Generated by: system Generated on: 01-Feb-2017 10:15:15 Page 4 of 4 BRAZILIAN PROFESSIONALS, LLC. 28001 Dorothy Drive 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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 207099.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

Department: CFSAN
CTU Triage Date 00 Forth-2017

Total Pages: 5

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

Receipt No: RCT-29568

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	01-Feb-2017	CTU Received Date	01-Feb-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	
Assign To	User		
User/Group			
Forward to Department	CDER		

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Generated by: system Generated on: 01-Feb-2017 11:45:13 Page 1 of 5

Department: CFSAN

Receipt No: RCT-29568 CTU Triage Date 00B Foetb-2017

	What kind of problem was it?	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		
		Noticed a problem with the quality of the product		
		Had problems after switching from one product maker to another maker		
	Did any of the following happen?	Hospitalization - admitted or stayed longer		
	(Check all that apply)	Required help to prevent permanent harm (for medical devices only)		
		Disability or health problem		
		Birth defect		
		Life-threatening		
		Death		
		Other serious/important medical incident		
	Date of Death			
	Other serious/important medical incident			
ŀ	Date the problem occurred	01-Feb-2017		
ТеТ	<u> </u>	happened (Include as many details as possible)		
TC		and while I was in the chair my whole body and face broke out in hives there was no ventilation		
	Thad a Brazman blowout treatment a	and while I was in the chair my whole body and face bloke out in mives there was no ventuation		
<u>_</u>				
LIS	t any relevant tests or laborato	ry data if you know them (Include dates)		
Sac	etion B - About the Products	1 of 1		
260				
	Name of the product as it appears on the box, bottle, or package	Brazilian blowout		
	on the box, bottle, or package			
	(Include as many names as you			
	(Include as many names as you see)			
-	see) Name of the company that makes	Brazilian blowout		
-	Name of the company that makes (or compounds) the product	Brazilian blowout		
	see) Name of the company that makes	Brazilian blowout		
	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether	Brazilian blowout		
-	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter?	Brazilian blowout Yes		
	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date			
	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number			
	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number	Yes		
	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per	Yes		
	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number	Yes		
	see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g)	Yes If Other		
	see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity	Yes If Other If Other		
	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started	Yes If Other If Other If Other		
	see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started taking or using the product	Yes If Other If Other If Other		
	Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started	Yes If Other If Other If Other		

Generated by: system Generated on: 01-Feb-2017 11:45:13 Page 2 of 5

Department: CFSAN CTU Triage Date 00B Foetb-2017

Receipt No: RCT-29568	CTU Triag & Da 1550 (B) Freely-2017	
person reduced the dose or stopped taking or using the product?	Total Pages: 5	
Did the problem return if the person started taking or using the product again?		
Do you still have the product in case we need to evaluate it?	No	
Why was the person using the pro	oduct? (such as what condition was it supposed to treat)	
Curly hair		
Section C - About the Medical De	vice	
Name of medical device		
Name of the company that makes the medical device		
Model #		
Catalog #		
Serial #		
Lot #		
Unique Identifier (UDI) #		
Expiry Date		
Was someone operating the medical device when the problem occurred?		
For implanted medical devices Of	NLY (such as pacemakers, breast implants, etc.)	
Date the implant was put in	Date the implant was taken out (If	
Date the implant was put in	relevant)	
Other identifying information (Tl	ne model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate	
them)	, , , , , , , , , , , , , , , , , , , ,	
Section D - About the Person Wh	o Had the Problem	
Person's Initials	(5) (6)	
Sex	Female	
Age (specify unit of time for age)	28 Year(s)	
Date of Birth		
Weight	56.25 kg(s)	
Ethnicity (Choose only one)	Not Hispanic/Latino American Indian or Alaskan Native	
Race (Choose all that apply)	Native Hawaiian or Other Pacific Islander	
	Asian	
	White	
	Black or African American	

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

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Department: CFSAN CTU Triage Dat 500B Foeb-2017

Receipt No: RCT-29568	CTU Triag& Dat 2500B Forth-2017
None	Total Pages: 5
Please list all allergies (such as to d	lrugs, foods, pollen or others)
List any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)
List all current prescription medic	ations and medical devices being used.
None	
List all over-the-counter medication	ons and any vitamins, minerals, supplements, and herbal remedies being used.
None	
OTHER (CONCOMITANT) MED	DICAL PRODUCTS 1 of 1
Product Name	
Strength	If Other
Therapy Start Date	
Therapy End Date	
Section E - About the Person Fillin	g Out This Form
Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	01-Feb-2017
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity	

Generated by: system Generated on: 01-Feb-2017 11:45:13 Page 4 of 5

Department: CFSAN

Receipt No: RCT-29568 CTU Triag & Dat 2500 Forth-2017

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

Generated by: system Generated on: 01-Feb-2017 11:45:13 Page 5 of 5

BRAZILIAN PROFESSIONALS, LLC. 28001 Dorothy Drive Agoura Hills, California 91301

To Whom It May Concern:

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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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 207103.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

Receipt No: RCT-30339 FDA 3500B Form

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

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	04-Feb-2017	CTU Received Date	04-Feb-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	
Assign To	User		
User/Group			
Forward to Department	CDER		

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	

Generated by: system **Generated on:** 04-Feb-2017 13:19:22 **Page 1 of 4**

CTU #: FDA-CDER-CTU-2017-6662 | Dept: CFSAN | RCT #: RCT-30339 | CTU Triage Date: 06-Feb-2017 | Total Pages: 4

Receipt No: RCT-30339 FDA 3500B Form

Se	ection A - About the Problem					
	What kind of problem was it?		ect (including new or worsening symptom	s)		
	(Check all that apply)	Used a product incorrectly which	ch could have or led to a problem			
		Noticed a problem with the qua	lity of the product			
		Had problems after switching f	rom one product maker to another maker			
	Did any of the following happen?	Hospitalization - admitted or st	Hospitalization - admitted or stayed longer			
	(Check all that apply)	Required help to prevent perma	Required help to prevent permanent harm (for medical devices only)			
		Disability or health problem	Disability or health problem			
		Birth defect	Birth defect			
		Life-threatening				
		Death				
		Other serious/important medica	al incident			
	Date of Death					
	Date the problem occurred	03-Feb-2017				
Те	ll us what hannened and how it	hannened (Include as mai	ny details as nossible)			
10	Tell us what happened and how it happened (Include as many details as possible) Severe red open rash on scalp. Severe itch.					
	Severe red open rash on scarp. Severe	FICH.				
Lis	st any relevant tests or laborator	ry data if you know them ((Include dates)			
~						
Se	ction B - About the Products			1 of 1		
Se	Name of the product as it appears	Tresemme Keratin Smooth		1 of 1		
Se	Name of the product as it appears on the box, bottle, or package	Tresemme Keratin Smooth		1 of 1		
Se	Name of the product as it appears	Tresemme Keratin Smooth		1 of 1		
Se	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes	Tresemme Keratin Smooth Unilever		1 of 1		
Se	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product			1 of 1		
Se	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded?			1 of 1		
Se	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be			1 of 1		
Se	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded?			1 of 1		
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether			1 of 1		
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	Unilever		1 of 1		
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter?	Unilever		1 of 1		
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date	Unilever		1 of 1		
Se	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number	Unilever	If Other	1 of 1		
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number	Unilever	If Other	1 of 1		
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per	Unilever	If Other	1 of 1 25 Ounce(s)		
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g)	Ves 05136JU34	If Other If Other			
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity	Ves 05136JU34	If Other			
Sed	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency	Ves 05136JU34 Other	If Other If Other	25 Ounce(s)		
Sec	Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started	Ves 05136JU34 Other	If Other If Other	25 Ounce(s)		

Generated by: system Generated on: 04-Feb-2017 13:19:22 Page 2 of 4

CTU #: FDA-CDER-CTU-2017-6662 | Dept: CFSAN | RCT #: RCT-30339 | CTU Triage Date: 06-Feb-2017 | Total Pages: 4

Receipt No: RCT-30339 product? Did the problem return if the Yes person started taking or using the product again? Do you still have the product in No case we need to evaluate it? Why was the person using the product? (such as what condition was it supposed to treat) Shampoo hair Section C - About the Medical Device Name of medical device Name of the company that makes the medical device Model# Catalog # Serial # Lot# Unique Identifier (UDI) # **Expiry Date** Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Section D - About the Person Who Had the Problem Person's Initials Female 47 Year(s) Age (specify unit of time for age) **Date of Birth** Weight Ethnicity (Choose only one) Not Hispanic/Latino Race (Choose all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Generated by: system Generated on: 04-Feb-2017 13:19:22 Page 3 of 4

CTU #: FDA-CDER-CTU-2017-6662 | Dept: CFSAN | RCT #: RCT-30339 | CTU Triage Date: 06-Feb-2017 | Total Pages: 4

Receipt No: RCT-30339 Please list all allergies (such as to drugs, foods, pollen or others) Levaquin List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1 **Product Name** If Other Strength **Therapy Start Date** Therapy End Date Section E - About the Person Filling Out This Form (b) (6) Last name First name (b) (6)Number/Street (b)(6)City (b)(6)State/Province USA Country (b)(6)ZIP or Postal code Telephone number **Email address** (b) (6) Today's date 04-Feb-2017 Did you report this problem to the No company that makes the product (the manufacturer/compounder)? If you do NOT want your identity disclosed to the manufacturer, place an X in this box:

Generated by: system Generated on: 04-Feb-2017 13:19:22 Page 4 of 4

UNILEVER UNITED STATES, INC. 920 Sylvan Avenue 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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 207239.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

CTU #: FDA-CDER-CTU-2017-11974 | Dept: CFSAN | RCT #: RCT-35880 | CTU Triage Date: 01-Mar-2017 | Total Pages: 4

Receipt No: RCT-35880

FDA 3500B Form Related reports

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

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212727 - Anonymous 1

Basic Details			The state of the s
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		-Mills
FDA Received Date	01-Mar-2017	CTU Received Date	01-Mar-2017
CTU Tringe Date		•	
Report Type	Spontaneous	Report Classification	
Assign To	User	· · · · · · · · · · · · · · · · · · ·	*
User/Group			
Forward to Department	CDER		

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
\square	0.0 (6)	(B) (U)		

Generated by: system Generated on: 01-Mar-2017 00:15:57 Page 1 of 4

CTU #: FDA-CDER-CTU-2017-11974 | Dept: CFSAN | RCT #: RCT-35880 | CTU Triage Date: 01-Mar-2017 | Total Pages: 4

Receipt No: RCT-35880 | FDA 3500B Form

	eccipt No. RC1-55000 FDA 5500B FOFIII				
Se	ction A - About the Problem				
	What kind of problem was it?	Were hurt or had a bad side eff	fect (including new or worsening symptom	s)	
	(Check all that apply)		ch could have or led to a problem		
		Noticed a problem with the qua	dity of the product		
		Had problems after switching f	rom one product maker to another maker		
	Did any of the following happen?	Hospitalization - admitted or stayed longer			
	(Check all that apply)	Required help to prevent permanent harm (for medical devices only)			
		Disability or health problem			
		Birth defect			
		Life-threatening			
		Death Other serious/important media	al insident		
		Other serious/important medica	ai meident		
	Date of Death	22.5.1.2015			
	Date the problem occurred	23-Feb-2017			
Te	ell us what happened and how it	happened (Include as mai	ny details as possible)		
	I am a hairstylist that works in salon that is part of a large chain of salons. We use a Keratin style hair smoother/straightener in our salon. The brand name is Liquid Keratin. The first time I used the product I felt ill. I have experienced horrible pressure in my head followed by a headache and sore throat that burned for days. At times I would feel extremely lightheaded. Each subsequent time I used the product I became ill with the same symptoms. These symptoms would continue to get worse even hours after the service was completed. It is during the blow dry process and flat iron stage that I begin to feel the onset of symptoms. Other stylists in the salon have felt the serious and adverse side effects as well. Burning eyes, almost fainting, headaches.				
List any relevant tests or laboratory data if you know them (Include dates)					
	Liquid Keratin claims to be "formald treatment. The MSDS states nothing carbocysteine is the second ingredien	about the chemical changes cau			
Se	ction B - About the Products			1 of 1	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Liquid Keratin			
	Name of the company that makes (or compounds) the product	Liquid Keratin			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?	Yes			
	Expiration date				
	Lot number				
	NDC number				
	Strength (for example, 250 mg per 500 ml or 1g)		If Other		
		0.4	1		
	Quantity	Other	If Other	1 Ounce(s)	
	Quantity Frequency	Other	If Other If Other	1 Ounce(s) At client request	
				` '	
	Frequency	Other	If Other	At client request	
	Frequency How was it taken or used Date the person first started	Other Other	If Other	At client request	

01-Mar-2017 00:15:57 Page 2 of 4 Generated by: system Generated on:

CTU #: FDA-CDER-CTU-2017-11974 | Dept: CFSAN | RCT #: RCT-35880 | CTU Triage Date: 01-Mar-2017 | Total Pages: 4

Receipt No: RCT-35880 product? Did the problem return if the Yes person started taking or using the product again? Do you still have the product in Yes case we need to evaluate it? Why was the person using the product? (such as what condition was it supposed to treat) Hair Smoothing Section C - About the Medical Device Name of medical device Name of the company that makes the medical device Model# Catalog # Serial # Lot# Unique Identifier (UDI) # **Expiry Date** Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Section D - About the Person Who Had the Problem Person's Initials (b) (6) Female Age (specify unit of time for age) 46 Year(s) **Date of Birth** Weight Ethnicity (Choose only one) Not Hispanic/Latino Race (Choose all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Generated by: system Generated on: 01-Mar-2017 00:15:57 Page 3 of 4

CTU #: FDA-CDER-CTU-2017-11974 | Dept: CFSAN | RCT #: RCT-35880 | CTU Triage Date: 01-Mar-2017 | Total Pages: 4 Receipt No: RCT-35880 Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1 **Product Name** If Other Strength **Therapy Start Date** Therapy End Date (b) (6) Last name (b) (6) First name Number/Street City State/Province USA Country

Section E - About the Person Filling Out This Form Last name (b) (6) First name (b) (6) Number/Street City State/Province Country USA ZIP or Postal code Telephone number Email address Today's date 01-Mar-2017 Did you report this problem to the company that makes the product (the manufacturer/compounder)? If you do NOT want your identity disclosed to the manufacturer, place an X in this box :

Generated by: system Generated on: 01-Mar-2017 00:15:57 Page 4 of 4

Receipt No: RCT-35880 FDA 3500B Form

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

Basic Details				
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
FDA Received Date	01-Mar-2017	CTU Received Date	01-Mar-2017	
CTU Triage Date				
Report Type	Spontaneous	Report Classification		
Assign To	User			
User/Group				
Forward to Department	CDER			

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)		

Generated by: system **Generated on:** 01-Mar-2017 00:15:57 **Page 1 of 4**

CTU #: FDA-CDER-CTU-2017-11974 | Dept: CFSAN | RCT #: RCT-35880 | CTU Triage Date: 01-Mar-2017 | Total Pages: 4

Receipt No: RCT-35880 | FDA 3500B Form

	eccipt No. RC1-55000 FDA 5500B FOFIII				
Se	ction A - About the Problem				
	What kind of problem was it?	Were hurt or had a bad side eff	fect (including new or worsening symptom	s)	
	(Check all that apply)		ch could have or led to a problem		
		Noticed a problem with the qua	dity of the product		
		Had problems after switching f	rom one product maker to another maker		
	Did any of the following happen?	Hospitalization - admitted or stayed longer			
	(Check all that apply)	Required help to prevent permanent harm (for medical devices only)			
		Disability or health problem			
		Birth defect			
		Life-threatening			
		Death Other serious/important media	al insident		
		Other serious/important medica	ai meident		
	Date of Death	22.5.1.2015			
	Date the problem occurred	23-Feb-2017			
Te	ell us what happened and how it	happened (Include as mai	ny details as possible)		
	I am a hairstylist that works in salon that is part of a large chain of salons. We use a Keratin style hair smoother/straightener in our salon. The brand name is Liquid Keratin. The first time I used the product I felt ill. I have experienced horrible pressure in my head followed by a headache and sore throat that burned for days. At times I would feel extremely lightheaded. Each subsequent time I used the product I became ill with the same symptoms. These symptoms would continue to get worse even hours after the service was completed. It is during the blow dry process and flat iron stage that I begin to feel the onset of symptoms. Other stylists in the salon have felt the serious and adverse side effects as well. Burning eyes, almost fainting, headaches.				
List any relevant tests or laboratory data if you know them (Include dates)					
	Liquid Keratin claims to be "formald treatment. The MSDS states nothing carbocysteine is the second ingredien	about the chemical changes cau			
Se	ction B - About the Products			1 of 1	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Liquid Keratin			
	Name of the company that makes (or compounds) the product	Liquid Keratin			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?	Yes			
	Expiration date				
	Lot number				
	NDC number				
	Strength (for example, 250 mg per 500 ml or 1g)		If Other		
		0.4	1		
	Quantity	Other	If Other	1 Ounce(s)	
	Quantity Frequency	Other	If Other If Other	1 Ounce(s) At client request	
				` '	
	Frequency	Other	If Other	At client request	
	Frequency How was it taken or used Date the person first started	Other Other	If Other	At client request	

01-Mar-2017 00:15:57 Page 2 of 4 Generated by: system Generated on:

CTU #: FDA-CDER-CTU-2017-11974 | Dept: CFSAN | RCT #: RCT-35880 | CTU Triage Date: 01-Mar-2017 | Total Pages: 4

Receipt No: RCT-35880 product? Did the problem return if the Yes person started taking or using the product again? Do you still have the product in Yes case we need to evaluate it? Why was the person using the product? (such as what condition was it supposed to treat) Hair Smoothing Section C - About the Medical Device Name of medical device Name of the company that makes the medical device Model# Catalog # Serial # Lot# Unique Identifier (UDI) # **Expiry Date** Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Section D - About the Person Who Had the Problem Person's Initials (b) (6) Female Age (specify unit of time for age) 46 Year(s) **Date of Birth** Weight Ethnicity (Choose only one) Not Hispanic/Latino Race (Choose all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Generated by: system Generated on: 01-Mar-2017 00:15:57 Page 3 of 4

CTU #: FDA-CDER-CTU-2017-11974 | Dept: CFSAN | RCT #: RCT-35880 | CTU Triage Date: 01-Mar-2017 | Total Pages: 4 Receipt No: RCT-35880 Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1 **Product Name** If Other Strength **Therapy Start Date** Therapy End Date (b) (6) Last name (b) (6) First name Number/Street City State/Province USA Country

Section E - About the Person Filling Out This Form Last name (b) (6) First name (b) (6) Number/Street City State/Province Country USA ZIP or Postal code Telephone number Email address Today's date 01-Mar-2017 Did you report this problem to the company that makes the product (the manufacturer/compounder)? If you do NOT want your identity disclosed to the manufacturer, place an X in this box :

Generated by: system Generated on: 01-Mar-2017 00:15:57 Page 4 of 4

LIQUID KERATIN INC 101 King High Ave Toronto, ON 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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 208370.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

Branch Chief, Signals Management Branch Division of Public Health Informatics &

Analytics

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

Receipt No: RCT-40789 FDA 3500B Form

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

Basic Details				
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
FDA Received Date	22-Mar-2017	CTU Received Date	22-Mar-2017	
CTU Triage Date				
Report Type	Spontaneous	Report Classification		
Assign To	User			
User/Group				
Forward to Department	CDER			

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Generated by: system **Generated on:** 22-Mar-2017 22:45:27 **Page 1 of 5**

CTU #: FDA-CDER-CTU-2017-16815 | Dept: CFSAN | RCT #: RCT-40789 | CTU Triage Date: 23-Mar-2017 | Total Pages: 5

Receipt No: RCT-40789 FDA 3500B Form

Se	ction A - About the Problem				
	What kind of problem was it?	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			
		Noticed a problem with the quality of the product			
		Had problems after switching from one product maker to another maker			
	Did any of the following happen?	Hospitalization - admitted or stayed longer			
	(Check all that apply)	Required help to prevent permanent harm (for medical devices only)			
		Disability or health problem			
		Birth defect			
		Life-threatening Death			
		Other serious/important medical incident			
	D	Other serious/important incucar incucar	4		
	Date of Death	Dissipate Gint and Griss			
	Other serious/important medical incident	Dizziness, faint, confusion			
	Date the problem occurred	22-Mar-2017			
Te	ll us what happened and how it	appened (Include as many details as possible)			
	I work in a hair salon. I was cutting my clients hair and began to feel dizzy I tried to keep my balance and readjust my head position so I wouldn't fall back. My heart started to race and I felt faint. I didn't know what I was saying or doing I just wanted to finish my client to sit down. I started to feel nauseous and finally left my station. After a few minutes I returned to my station and the feelings came back I had to shut my eyes and couldn't talk I realized another stylist was doing a Brazilian Blowout near me I immediately left my symptoms slowly got better My eyes were burning and my nose and throat are very dry/scratchy. Even into the evening Mu salon started to carry the Brazilian blowout over the past 6-8 months and I have had mild dizziness before but never understood why or how but it has only been at work within that time frame. Never anywhere else!				
T i	st any relevant tests or laborate	data if you know them (Include dates)			
	st any refevant tests of faborator	data if you know them (include dates)	-		
Se	ction B - About the Products	1 of 1			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout			
	Name of the company that makes (or compounds) the product				
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?				
	Expiration date				
	Lot number				
	NDC number				
	Strength (for example, 250 mg per 500 ml or 1g)	If Other			
	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	15-Sep-2016			

Generated by: system Generated on: 22-Mar-2017 22:45:27 Page 2 of 5

CTU #: FDA-CDER-CTU-2017-16815 | Dept: CFSAN | RCT #: RCT-40789 | CTU Triage Date: 23-Mar-2017 | Total Pages: 5

Receipt No: RCT-40789 Did the problem stop after the Yes person reduced the dose or stopped taking or using the product? Did the problem return if the Yes person started taking or using the product again? Yes Do you still have the product in case we need to evaluate it? Why was the person using the product? (such as what condition was it supposed to treat) Hair frizz **Section C - About the Medical Device** Name of medical device Name of the company that makes the medical device Model# Catalog # Serial # Lot# Unique Identifier (UDI) # **Expiry Date** Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Section D - About the Person Who Had the Problem Person's Initials (b) (6) Sex Female Age (specify unit of time for age) 43 Year(s) **Date of Birth** Weight 67.5 kg(s) **Ethnicity (Choose only one)** Not Hispanic/Latino American Indian or Alaskan Native Race (Choose all that apply) Native Hawaiian or Other Pacific Islander Asian White Black or African American

Generated by: system Generated on: 22-Mar-2017 22:45:27 Page 3 of 5

CTU #: FDA-CDER-CTU-2017-16815 | Dept: CFSAN | RCT #: RCT-40789 | CTU Triage Date: 23-Mar-2017 | Total Pages: 5 Receipt No: RCT-40789 List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Please list all allergies (such as to drugs, foods, pollen or others) Seasonal List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. Daily gummy vitamin

OTHER (CONCOMITANT) MED	OICAL PRODUCTS		1 of 1
Product Name			
Strength	I	If Other	
Therapy Start Date			
Therapy End Date			

ection E - About the Person Fillir	ng Out This Form
Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	(b) (6)
Did you report this problem to the company that makes the product	No

Generated by: system Generated on: 22-Mar-2017 22:45:27 Page 4 of 5 CTU #: FDA-CDER-CTU-2017-16815 | Dept: CFSAN | RCT #: RCT-40789 | CTU Triage Date: 23-Mar-2017 | Total Pages: 5

Generated by: system **Generated on:** 22-Mar-2017 22:45:27 **Page 5 of 5**

Receipt No: RCT-53393 FDA 3500B Form

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

Basic Details					
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
FDA Received Date	15-May-2017	CTU Received Date	15-May-2017		
CTU Triage Date					
Report Type	Spontaneous	Report Classification			
Assign To	User				
User/Group					
Forward to Department	CDER				

Contact							
Source Form Type	First Name	Last Name	Email Address	Phone			
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)			

Generated by: system **Generated on:** 15-May-2017 20:45:08 **Page 1 of 5**

Receipt No: RCT-53393 FDA 3500B Form

What kind of problem was it? (Check all that apply) Did any of the following happen? (Check all that apply) Did any of the following happen? (Check all that apply) Did any of the following happen? (Check all that apply) Did any of the following happen? (Check all that apply) Did any of the following happen? (Check all that apply) Did any of the following happen? (Check all that apply) Did by the following happen? Did by the following happen? (Check all that apply) Did by the following happen? Did by	Sec	ction A - About the Problem				
Did any of the following happen? (Check all that apply) Required help to prove premanent hum (for modical devices only) Did any of the following happen? Required help to prevent premanent hum (for modical devices only) Did any of the following happen? Check all that apply) Did any of the following happen? Required help to prevent premanent hum (for modical devices only) Did help to be the product of the p		What kind of problem was it?	Were hurt or had a bad side	effect (including new or worsening sympton	ns)	
Did any of the following happen? (Check all that apply) Did any of the following happen? Check all that apply) Did any of the following happen? Check all that apply) Did any of the following happen? Check all that apply) Did any of the following happen? Check all that apply) Did any of the following happen? Check all that apply) Did any of the following happen? Date of Death			Used a product incorrectly w	hich could have or led to a problem		
Did any of the following happen? (Check all that apply) Required hole to preven permanent humn (for medical devices only) Did by the product of the product of the product of the product of the product of the product of the product of high amounts of formal delay feet in section of the product of high amounts of the product of the own product of high amounts of the product			Noticed a problem with the q	uality of the product		
Check all that apply) Required tolp to proven permanent harm (for medical devices only) Reduity or health problem Required tolp to proven permanent harm (for medical devices only) Reduity or health problem Required tolp to the serious/important medical incident			Had problems after switching	g from one product maker to another make	r	
Disability or health problem		Did any of the following happen?	Hospitalization - admitted or	stayed longer		
Date of Death Date the problem occurred 12-Apr-2017 Tell us what happened and how it happened (Include as many defails as possible) I received a keratin hair treatment on April 12th, 2017 and I've been sick ever since. I had a metallic taste of my mouth for three weeks, I've been daze, Aint, nausceus, having heart applications and digestive issues. I actually bought a tongue scraper to take off the taste in my mouth. Since then, I'm extremely sensitive to any type of chemical smell even Tide detergent pods. Anything that has a low, medium on high VOC affects me. I'm deciple concerned that the product I seek has formaldelyde in it data may accussed this reaction. I bought the product from Amazon last May 2016. I didn't use it right away because I didn't need it until one month ago before taking a vacation in Costa Rica. I had two sets to blood work done on an April 24th and one on May 9 had an three are abnormalities sepace action. I bought the product from Amazon last May 2016. I didn't use it right away because I didn't need it until one month ago before taking a vacation in Costa Rica. I had two sets of blood work done on Amazon. I would like to get the product tested to find out if I've been exposed to high amounts of formaldelydes. Every time I wash my hat the small emits into the air, so I've been going I - 2 weeks without washing my find out what's in it. I need to resolve the way I'm feeling as I need to work and be functional. List any relevant tests or laboratory data if you know them (Include dates) I have blood tests from my doctor; I'm still under his care and would like to get to the bottom of this challenge. Section B - About the Products Name of the product as it appears on the loss, bottle, or package (Include as amay names as you see) Name of the company that makes for compounded? Your health professional may be able to help you identify whether the drug was compounded.) Expiration date Lot number NDC number Strength (for example, 250 mg per 800 mi) or 1g) Unantify Frequency If		(Check all that apply)	Required help to prevent per	manent harm (for medical devices only)		
Date of Death Date the problem occurred 12-Apr-2017			Disability or health problem			
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Date of Death Date the problem occurred 12-Apr-2017			Life-threatening			
Date of Death Date the problem occurred 12-Apr-2017 Tell us what happened and how it happened (Include as many details as possible) I received a keratin hair reatment on April 12th, 2017 and I've been sick ever since. I had a metallic taste of my mouth for three weeks, I've been dizzy, faint, nauscous, having heat palpitations and digestive issues, I actually bought a tongue scraper to take off the taste in my mouth. Since after, I've been dizzy, faint, nauscous, having heat palpitations and digestive issues, I actually bought a tongue scraper to take off the taste in my mouth. Since after, I've been dizzy, faint, nauscous, having heat palpitations and digestive issues, I actually bought at tongue scraper to take off the taste in my mouth. Since after a possible of the same of the control of the problem of			Death			
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		Date the person first started	12-Apr-2017	•	•	
			•			

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Receipt No: RCT-53393 using the product Did the problem stop after the No person reduced the dose or stopped taking or using the product? Did the problem return if the Doesn't Apply person started taking or using the product again? Do you still have the product in Yes case we need to evaluate it? Why was the person using the product? (such as what condition was it supposed to treat) To control frizz and smooth my hair Section C - About the Medical Device Name of medical device Name of the company that makes the medical device Model # Catalog # Serial # Lot# Unique Identifier (UDI) # **Expiry Date** Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Section D - About the Person Who Had the Problem Person's Initials (b)(6)Sex Female Age (specify unit of time for age) 49 Year(s) **Date of Birth** Weight 49.5 kg(s) **Ethnicity (Choose only one)** Not Hispanic/Latino Race (Choose all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian

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White

Black or African American

Receipt No: RCT-53393 List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Hypothyroid Please list all allergies (such as to drugs, foods, pollen or others) Penicillin, pollen, rag weed, mold, oak trees, dust List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) I'm a very healthy person that eats mostly organic vegetables and fish. I'm also a integrative health coach. List all current prescription medications and medical devices being used. Nature Thyroid List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. Nothing OTHER (CONCOMITANT) MEDICAL PRODUCTS **Product Name** If Other Strength **Therapy Start Date Therapy End Date** Section E - About the Person Filling Out This Form (b)(6)Last name First name (b) (6) Number/Street (b)(6)City (b) (6) State/Province USA Country ZIP or Postal code (b) (6) Telephone number (b)(6)**Email address** (b) (6) Today's date 15-May-2017 Did you report this problem to the No company that makes the product

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Receipt No: RCT-53393 FDA 3500B Form

(the manufacturer/compounder)?

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

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Receipt No: RCT-35880

FDA 3500B Form Related reports

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

208370

212727 - Anonymous 1

Basic Details			GIRTH THISTIPHENE
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		- Mile
FDA Received Date	01-Mar-2017	CTU Received Date	01-Mar-2017
CTU Tringe Date		•	•
Report Type	Spontaneous	Report Classification	
Assign To	User	· · · · · · · · · · · · · · · · · · ·	
User/Group			
Forward to Department	CDER		

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
	0.0 (6)	(B) (U)		

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CTU #: FDA-CDER-CTU-2017-11974 | Dept: CFSAN | RCT #: RCT-35880 | CTU Triage Date: 01-Mar-2017 | Total Pages: 4

Receipt No: RCT-35880 | FDA 3500B Form

			F	
Se	ction A - About the Problem			
	What kind of problem was it?	Were hurt or had a bad side eff	ect (including new or worsening symptom	s)
	(Check all that apply)	Used a product incorrectly which could have or led to a problem		
		Noticed a problem with the qua	dity of the product	
		Had problems after switching f	rom one product maker to another maker	
	Did any of the following happen?	Hospitalization - admitted or st	ayed longer	
	(Check all that apply)	Required help to prevent perms	anent harm (for medical devices only)	
		Disability or health problem		
		Birth defect		
		Life-threatening		
		Death Other serious/important medical	al insident	
		Other serious/important medica	ai meident	
	Date of Death	22 F 1 2017		
	Date the problem occurred	23-Feb-2017		
Te	ell us what happened and how it	happened (Include as mai	ny details as possible)	
	I am a hairstylist that works in salon of the brand name is Liquid Keratin. The headache and sore throat that burned became ill with the same symptoms. It be blow dry process and flat iron stagadverse side effects as well. Burning	ne first time I used the product I for days. At times I would feel of These symptoms would continu ge that I begin to feel the onset of	felt ill. I have experienced horrible extremely lightheaded. Each subsequence to get worse even hours after the soft symptoms. Other stylists in the same	pressure in my head followed by a quent time I used the product I service was completed. It is during
T :	st any relevant tests or laborator	ey data if you know tham	(Include dates)	
	Liquid Keratin claims to be "formaldehyde free." The manufacturers directions state to heat the flat iron to 420 to 450 degrees during the treatment. The MSDS states nothing about the chemical changes caused by the heat. There are no warnings on the label. Glyoxyloyl carbocysteine is the second ingredient listed on the bottle.			
Se	ction B - About the Products			1 of 1
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Liquid Keratin		
	Name of the company that makes (or compounds) the product	Liquid Keratin		
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
	Is the Product Over-the-Counter?	Yes		
	Expiration date			
	Lot number			
	NDC number			
	Strength (for example, 250 mg per 500 ml or 1g)		If Other	
	Quantity	Other	If Other	1 Ounce(s)
1	Quantity			1 Ounce(s)
	Frequency	Other	If Other	At client request
		Other Other	If Other If Other	` '
	Frequency			At client request
	Frequency How was it taken or used Date the person first started	Other		At client request

01-Mar-2017 00:15:57 Page 2 of 4 Generated by: system Generated on:

Receipt No: RCT-35880 product? Did the problem return if the Yes person started taking or using the product again? Do you still have the product in Yes case we need to evaluate it? Why was the person using the product? (such as what condition was it supposed to treat) Hair Smoothing Section C - About the Medical Device Name of medical device Name of the company that makes the medical device Model# Catalog # Serial # Lot# Unique Identifier (UDI) # **Expiry Date** Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Section D - About the Person Who Had the Problem Person's Initials (b) (6) Female Age (specify unit of time for age) 46 Year(s) **Date of Birth** Weight Ethnicity (Choose only one) Not Hispanic/Latino Race (Choose all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

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CTU #: FDA-CDER-CTU-2017-11974 | Dept: CFSAN | RCT #: RCT-35880 | CTU Triage Date: 01-Mar-2017 | Total Pages: 4 Receipt No: RCT-35880 Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1 **Product Name** If Other Strength **Therapy Start Date** Therapy End Date (b) (6) Last name (b) (6) First name Number/Street City State/Province USA Country

Section E - About the Person Filling Out This Form Last name (b) (6) First name (b) (6) Number/Street City State/Province Country USA ZIP or Postal code Telephone number Email address Today's date 01-Mar-2017 Did you report this problem to the company that makes the product (the manufacturer/compounder)? If you do NOT want your identity disclosed to the manufacturer, place an X in this box :

Generated by: system Generated on: 01-Mar-2017 00:15:57 Page 4 of 4

LIQUID KERATIN INC 101 King High Ave Toronto, ON 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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 212727.

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,

Lyle Canida, Pharm.D., M.S.

LCDR, U.S. Public Health Service

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Enclosure

Receipt No: RCT-64680 FDA 3500B Form

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

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	29-Jun-2017	CTU Received Date	29-Jun-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	
Assign To	User		
User/Group			
Forward to Department	CDER		

Contact				
Source Form Type	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)		

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CTU #: FDA-CDER-CTU-2017-40417 | Dept: CFSAN | RCT #: RCT-64680 | CTU Triage Date: 29-Jun-2017 | Total Pages: 4

Receipt No: RCT-64680

FDA 3500B Form

Rec	eipt No: RC1-04060		1	DA 3500B FORM	
Sec	ction A - About the Problem				
	What kind of problem was it?	Were hurt or had a bad side	effect (including new or worsening symptom	s)	
	(Check all that apply)	Used a product incorrectly w	vhich could have or led to a problem		
		Noticed a problem with the o	quality of the product		
		Had problems after switchin	g from one product maker to another maker		
	Did any of the following happen?	Hospitalization - admitted or	r stayed longer		
	(Check all that apply)	Required help to prevent per	rmanent harm (for medical devices only)		
		Disability or health problem			
		Birth defect			
		Life-threatening			
		Death			
		Other serious/important med	dical incident		
	Date of Death				
	Date the problem occurred	31-Jul-2016			
Та	ll us what happened and how it	hannanad (Includa as m	any dataile ae noccibla)		
16		*		Maggive amount of shedding tool	
	Received a Brazilian Blowout Smooth place. Scalp was red and itchy and but regrowth. I have miniaturized superflit to the treatment, I had no scalp issues looking at hair toppers and starting to going through the same after Brazilia.	arned. Have lost at least 60% luous hairs and scalp is still rest and long, extremely thick hap go through a deep depression	of hair thickness. I still have hair loss ed. My hair continues to thin and scaluir. There is no hair loss issues in any n. There are many blogs and support	from the bulb with little or no p goes from pink to beet red. Prior of my family members. I have been groups on line and many women are	
Lis	t any relevant tests or laborator	rv data if you know ther	n (Include dates)		Ī
	I've been to 7 dermatologist and an ac effluvium and would get better when with red scalp and continued diffused	the scalp inflammation is gor			
C	C D AL AL D LA			1 61	
Sec	ction B - About the Products			1 of 1	
	Name of the product as it appears on the box, bottle, or package	Brazilian Blowout			
	(Include as many names as you				
	see)				
	Name of the company that makes (or compounds) the product	I don't know. It's from Hair	salon		
	Is the Product Compounded?				
	(Your health professional may be				
	able to help you identify whether				
	the drug was compounded.)				
	Is the Product Over-the-Counter?				
	Expiration date				
	Lot number				
	NDC number		16 0/1		
	Strength (for example, 250 mg per 500 ml or 1g)		If Other		
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Topical	If Other		
	Date the person first started taking or using the product	31-Jul-2016			
	Date the person stopped taking or	31-Jul-2016			
	using the product Did the problem stop after the	No			
	person reduced the dose or	110			
	stopped taking or using the	i			

29-Jun-2017 10:15:38 Page 2 of 4 Generated by: system Generated on:

CTU #: FDA-CDER-CTU-2017-40417 | Dept: CFSAN | RCT #: RCT-64680 | CTU Triage Date: 29-Jun-2017 | Total Pages: 4

Receipt No: RCT-64680 product? Did the problem return if the Doesn't Apply person started taking or using the product again? Do you still have the product in No case we need to evaluate it? Why was the person using the product? (such as what condition was it supposed to treat) Hair treatment at salon to smooth hair, eliminate frizz Section C - About the Medical Device Name of medical device Name of the company that makes the medical device Model# Catalog # Serial # Lot# Unique Identifier (UDI) # **Expiry Date** Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate Section D - About the Person Who Had the Problem Person's Initials Female Age (specify unit of time for age) 64 Year(s) **Date of Birth** Weight 49.05 kg(s) Ethnicity (Choose only one) Not Hispanic/Latino Race (Choose all that apply) American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White Black or African American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Borderline high blood pressure

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CTU #: FDA-CDER-CTU-2017-40417 | Dept: CFSAN | RCT #: RCT-64680 | CTU Triage Date: 29-Jun-2017 | Total Pages: 4

FDA 3500B Form

Receipt No: RCT-64680

Please list all allergies (such as to o	lease list all allergies (such as to drugs, foods, pollen or others)		
Macrodantin, keflex			
List any other important informat	tion about the person (such as smoking, pregnancy, alcohol use, etc.)		
List all current prescription medic	cations and medical devices being used.		
Losartan 25mg			
List all over-the-counter medication	ons and any vitamins, minerals, supplements, and herbal remedies being used.		
Calcium, vitamin D, Biotin, Fish Oil,	Grapeseed		
OTHER (CONCOMITANT) MEI	DICAL PRODUCTS 1 of 1		
Product Name			
Strength	If Other		
Therapy Start Date			
Therapy End Date			
Section E - About the Person Fillin	ng Out This Form		
Last name	(b) (6)		
First name	(b) (6)		
Number/Street			
City			
State/Province			
Country	USA		
	00/1		
ZIP or Postal code			
ZIP or Postal code Telephone number Email address			
Telephone number Email address			
Telephone number Email address Today's date	29-Jun-2017		
Telephone number Email address Today's date Did you report this problem to the company that makes the product	29-Jun-2017		
Telephone number Email address Today's date Did you report this problem to the company that makes the product (the manufacturer/compounder)?	29-Jun-2017 No		
Telephone number Email address Today's date Did you report this problem to the company that makes the product (the manufacturer/compounder)? If you do NOT want your identity	29-Jun-2017		
Telephone number Email address Today's date Did you report this problem to the company that makes the product (the manufacturer/compounder)?	29-Jun-2017 No		

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From: The Rose Sheet Katz Linda Subject: "The Rose Sheet" | This Week"s Issue Monday, September 22, 2014 4:07:16 AM Date: 2 Specialized coverage of regulatory, legislative, scientific, retailer/e-tailer, financial, marketing and legal news across the cosmetics, skin-care and fragrance industries. About Staff Free Trial Subscribe/Renew Advertise Monday, September 22, 2014 View in Browser Forward to a Friend Top Stories Short Window For Senate, House To Agree On TEA Review Deadlines For FDA The Senate approves an amended version of the Sunscreen Innovation Act by unanimous consent, with a view toward speeding FDA reviews for all OTC ingredient TEAs. The House version addresses only sunscreen TEAs, and reconciliation of the two chambers' bills likely will have to wait for the lame duck session. "The Rose Sheet" September 18 2014 9:50 AM CIR Panel Rejects Safe Use Of Hydroquinone Under UV Nail Lights At its September meeting, the Cosmetic Ingredient Review Expert Panel concluded that hydroquinone's use in gel nail products is safe when LED lights are used in the curing process, but UV lights should not be used to set formulas due to concerns about skin-cancer risks. Separately, panel members issued a final amended assessment for preservative methylisothiazolinone, affirming their earlier tentative decision on the ingredient's safety in rinse-off and leave-in products. "The Rose Sheet" September 22 2014 12:01 AM California DTSC's Draft Work Plan Includes Personal Care, But Few Surprises California's Department of Toxic Substances has identified "beauty, personal care and hygiene" as one of seven product categories that could yield nextround priority product selections under the state's Safer Consumer Products regulations. PCPC's Associate General Counsel (b) (6) says there are no big surprises in the nomination or the candidate chemicals identified - including formaldehyde, lead and phthalates - and he welcomed the direction DTSC appears to be taking toward more active industry engagement over the next three years. "The Rose Sheet" September 18 2014 3:55 PM ? The Marketplace

Cosmetics Sector Increasingly Popular Class-Action Target During H1 2014 From January to June 2014, complaints against cosmetics firms accounted for 11% of total U.S. filings alleging unfair and deceptive acts and practices, compared with 7% in 2013, according to law firm Bryan Cave LLP. Most often filed in California state and federal courts, complaints target "natural" and performance claims, among others identified in a "Rose Sheet" infographic.

"The Rose Sheet" September 19 2014 10:40 AM

Business & Finance

L'Oreal Brazil's Niely Buy Enhances Firm's Prospects In Hair-Care Hot Spot With the acquisition of Niely Cosmeticos, L'Oreal rounds out its hair-product portfolio in Brazil with lower-priced brands Cor & Ton and Niely Gold, reinforcing its No. 1 and No. 2 positions in hair color and hair care in the country's mass market. In a Sept. 15 report, UBS analyst Eva Ouiroga discusses the firm's optimistic prospects in Brazil, currently its sixth-biggest market and third-largest growth contributor. "The Rose Sheet" September 17 2014 3:20 PM

Marketing/Advertising

Olay Can Claim Benefit Over, But Not "Harshness" Of, Dove Body Wash - NAD P&G's LCAT testing is sufficient to support a claim in Olay Sensitive Body Wash ads that competing product Dove Sensitive Skin is more drying than water over time. However, the firm should discontinue claims that disparage the Dove offering as "harsh" or suggest that Dove Sensitive Skin users will perceive a drying effect upon contact or have noticeably drier skin with continued product use, NAD says.

"The Rose Sheet" September 22 2014 12:00 AM

NAD Rules On P&G Claims Comparing Olay, Dove Hydrating Body Washes Procter & Gamble's study data is sufficient to support claims that Olay Ultra Moisture Body Wash provides a greater long-term moisturization benefit compared with Unilever's Dove Deep Moisture, NAD rules. However, claims positioning the Olay product as a viable substitute for lotion should be discontinued, as should statements that tend to falsely disparage Unilever's competing body wash, the CBBB investigative unit says.

"The Rose Sheet" September 22 2014 12:00 AM

Trademarks

Weekly Trademark Review Sep 16, 2014 [Class 3 (Cosmetics and Cleaning Preps) compiled by "The Rose Sheet" from Official Gazette of the U.S. Patent and Trademark Office] Product Name Trademark No./ [Serial No.] Company Filed Date [Published] Class Nos.

"The Rose Sheet" September 22 2014 12:00 AM

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From: The Rose Sheet To: Katz, Linda Subject: "The Rose Sheet" | This Week"s Issue Date: Monday, October 6, 2014 4:06:15 AM i 7 2 Specialized coverage of regulatory, legislative, scientific, retailer/e-tailer, financial, marketing and legal news across the cosmetics, skin-care and fragrance industries. About | Staff | Free Trial | Subscribe/Renew | Advertise Monday, October 06, 2014 | View in Browser | Forward to a Friend **Top Stories** Preservatives Identified As Sustainability Priority At Industry Summit Held by Forum for the Future and co-hosted by Walmart and Target, the Sept. 4 Beauty and Personal Care Products Sustainability Summit facilitated discussion among entities throughout the supply chain regarding sustainability priorities and potential initiatives for improvement. Attendees identified development of new and alternative preservative systems as a key "idea for action," along with measures for enhanced communication and transparency around cosmetic ingredients. FTC: All Advertisers Should Heed Lessons From "Operation Full Disclosure" On the heels of FTC's "Operation Full Disclosure," which resulted in 60 warning letters, commission officials advise all advertisers to pay close attention to their disclosures and ensure they are clear and conspicuous. The initiative included review of 1,000 national television and print ads, and the agency says it will continue to monitor the advertising landscape for inadequate disclosure use. Safe Cosmetics Campaign Prepares "Retailer Red List" Of 100 "Toxic" Chemicals Within the next month, NGO will present retailers with a list of roughly 100 priority "toxic" chemicals it wants removed from personal-care products on store shelves, according to Campaign for Safe Cosmetics co-founder (b) (6) . Meanwhile, CSC has launched its "Cosmetics Without Cancer" initiative, with P&G as its initial target, part of an effort to reassess the market 10 years after creation of the Safe Cosmetics Compact.

Regulatory/Legislative

Sen. Feinstein Plans Cosmetics Bill In Collaboration With Industry, NGOs Prospects for the developing draft bill are optimistic given the California democratic senator's reputation for working "effectively across the aisle" and her receptivity to both industry and NGO stakeholders. (b) (6) co-founder of the Campaign for Safe Cosmetics, says the legislation will pick up where negotiations between FDA and industry left off earlier in 2014.

Europe Bans Preservative Mixture MCI/MI In Leave-On Cosmetics By July 16, 2015, cosmetics manufacturers will be prohibited from marketing leave-on products in Europe that contain a preservative mixture of methylchloroisothiazolinone and methylisothiazolinone under a ban the Cosmetic Ingredient Review Expert Panel anticipated with concern in recent meetings. Simultaneously, the EC announces stricter limits on propylparaben and butylparaben in personal-care items.

The Marketplace

Nutricosmetics Firms' Science, Innovation May Win Over "Trusting" Youth Exclusive online-only content>>>In a Datamonitor global survey of consumers between the ages of 18 and 34, 41% of respondents found nutricosmetic claims to be "somewhat or completely trustworthy." signaling opportunity in a category that has been limited in part by consumer skepticism. Datamonitor researcher Aleksandrina Yotova profiles winning innovations and strategies in the niche nutricosmetics segment.

P&G Crest Whitestrips Patents Stand Up To 'Indefiniteness' Challenge P&G prevalls In U.S. district court arguing that three private-label tooth-whitening-strip firms infringed three of its patents for Crest Whitestrips. The defendants plan to appeal the ruling against their motion that two of P&G's patents are invalid.

Other

P&G Is "First Target" Of CSC's "Cosmetics Without Cancer" Campaign Campaign for Safe Cosmetics initiative for Breast Cancer Awareness Month makes P&G its "first target," calling on the firm to discontinue use of formaldehyde-releasing preservatives and other alleged cancer-causing chemicals in its personal-care products. According to the NGO, products from Pantene, CoverGirl, Olay, Herbal Essences and Max Factor, among other P&G brands, contain substances that could be contributing to rising breast-cancer rates.

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From: The Rose Sheet Katz Linda Subject: "The Rose Sheet" | This Week"s Issue Monday, August 18, 2014 4:04:08 AM Date: 21 Specialized coverage of regulatory, legislative, scientific, retailer/e-tailer, financial, marketing and legal news across the cosmetics, skin-care and fragrance industries. Our digital media survey is now open! Take our 10 minute confidential survey on digital media and the future of our publications for the chance to win a MacBook Air. About Staff Free Trial Subscribe/Renew Advertise Monday, August 18, 2014 | View in Browser | Forward to a Friend Top Stories FDA Studies Trace Element Content In Cosmetics; Guidance To Come? In a study recently published in the Journal of Cosmetic Science, FDA assessed levels of seven trace contaminants in 150 cosmetic products on the market. The agency says the survey will help it to "make appropriate decisions regarding elemental contaminants in cosmetics." "The Rose Sheet" August 15 2014 9:50 AM Without User Fees, FDA's Monograph Review Process Lacks Manpower FDA's work on time-and-extent applications and monograph updates, unlike its work in evaluating NDAs for some OTC drugs and for Rx products, is not supported by user fees. The difference shows in the stalled process for approving new monograph ingredients, says the acting head of FDA's OTC drugs office. "The Rose Sheet" August 18 2014 12:00 AM Fast-Growing Glop & Glam To Cuddle With SoCozy In Children's Hair Care While recent sales declines in children's hair care speak to challenges in the segment, brands such as Glop & Glam have carved out successful niches particularly in the salon channel. Newcomer SoCozy hopes to make a similar impression with its line of kids' hair-care products with "a cool urban flair." "The Rose Sheet" August 18 2014 12:00 AM 2

Regulatory/Legislative

Dr. Bronner's Draws FDA Warning For Coconut Oil Disease Claim According to FDA, (b) (6) Magic "All-Onel" organic virgin coconut oil is an unapproved new drug based on a labeling claim indicating cholesterol benefits and, by extension, reduced coronary heart disease risk.

"The Rose Sheet" August 18 2014 12:00 AM

N.Y. Sen. Gillibrand Seeks Federal Action On Personal-Care Microbeads A federal interagency task force should include microbeads and microplastics from personal-care products on its list of Great Lakes contaminants, New York Senatoi(b) (6) asserts in a letter to EPA Administrator Gina McCarthy. The move would generate more in-depth study of the ingredients and allow for "the development of proper remediation."

"The Rose Sheet" August 18 2014 12:00 AM

New Products

New Products In Brief: Hue For Every Man, New Colgate Mouthwash; Vita Coco Oil; More Luxury grooming line Hue For Every Man launches, aimed at the multicultural market, Colgate Total Lasting White Mouthwash debuts; Vita Coco expands into coconut oil for culinary and beauty purposes. More new products.

"The Rose Sheet" August 18 2014 12:00 AM

Marketing/Advertising

Anti-Aging Claims For Jidue Facial-Massage Device Unsupported - ERSP Audy Global Enterprises' 30-subject study evaluating the Jidue Puffy Eye Treatment device was insufficient support for the firm's "clinically proven" claims, as well as its general performance claims in the context of targeted broadcast and online advertising, according to ERSP "The Rose Sheet" August 18 2014 12:00 AM

In Brief

In Brief NRC Upholds Formaldehyde As Known Carcinogen The National Research Council has upheld the National Toxicology Program's listing of formaldehyde as a known human carcinogen on its 12th Report on Carcinogens, according to an Aug. 7 release. NTP upgraded formaldehyde from "reasonably anticipated to be a human carcinogen" to the "known human carcinogen" level on the ROC in 2011 ("NTP Determines Formaldehyde "Known Human Carcinogen" In New Report" - "The Rose Sheet," Jun. 20, 2011). NRC has reviewed that decision and "found that the listing is supported by sufficient evidence fro "The Rose Sheet" August 18 2014 12:00 AM

Trademarks

Weekly Trademark Review Aug 12, 2014 [Class 3 (Cosmetics and Cleaning Preps) compiled by "The Rose Sheet" from Official Gazette of the U.S. Patent and Trademark Office] Product Name Trademark No./ [Serial No.] Company Filed Date [Published] Class Nos.

"The Rose Sheet" August 18 2014 12:01 AM

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