Triage unit sequence #

MEDWATCH

The FDA Safety Information and

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

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

A. PATIENT IN		54.	and a residence	2. Dose or Amo	ount	Frequency	Route	
1. Patient Identifier b) (6)	Age at Time of Event of Date of Birth: Years	7 3. Sex	4. Weight 200 lb	#1			-	
In confidence	(b) (6)	☐ Male	orkg					
	EVENT, PRODUCT P		and the second	3. Dates of Use (f (or best estimat #1 04/09/2014	e)	duration) from	Stopped	Abated After Use for Dose Reduced? es \[\text{No} \] \[\text{Dose}
	rror Problem with Diffe			#2			#2 🗆 Y	es No Doe
(Check all that app	_ Di	sability or Permanen	t Damage	4. Diagnosis or R #1 to conditi		(Indication)	8. Event	Reappeared After roduction?
Life-threatening		ongenital Anomaly/Bi		#2 6. Lot#	7 5	xpiration Date		es No Doe
	- initial or prolonged 🗸 Ot vention to Prevent Permane			#1 02254JU36	#1	xpiration Date		# or Unique ID
3. Date of Event (mi	m/dd/yyyy) 4. E	ete of this Report	mm/dd/yyyy)	#2	#2			
04/09/2014 5 Describe Event I	Problem or Product Use E	1/11/2014		E. SUSPECT 1. Brand Name	MEDICAL	DEVICE	Todan Toda	
On Wednesday Everstrong s	April 9th I washe hampoo. Then used (new to me). Some	ed my haid wit Suave Keratin	infusion	2. Common Device	e Name			COMPANY II
	head and around n						ą.	CTU
shower and c	eel scrub stuff. The living of the structure of the struc	ne mirror to co	omb hair	3. Manufacturer N	lame, City and	State	APR	1 4 2014
the next day	r). My back was ito for my back had a	thy and when I	looked	4. Model #	L	ot#		5. Operator of Dev
				Catalog #	E	xpiration Dat	e (mm/dd/yyyy)	Lay User/Patien
6. Relevant Tests/L	aboratory Data, Including	Dates		Serial#	0	ther#		
				6. If Implanted, Gi	ve Date (mm/d	(d/yyyy) 7.	If Explanted, G	ive Date (mm/dd/yyy
				8. Is this a Single	With the part of the second section of the	at was Repro	cessed and Re	used on a Patient?
				9. If Yes to Item No		and Address	of Reprocessor	
allergies, race, pre Race: White	istory, Including Preexisti gnancy, smoking and alcoh			F. OTHER (C	Charles and the Park		A-101-3-17-20-00-10-	-
Medical Cond	iitions:			Troduct rializes of	in merupy and	es jezande ir.	Sumon or Gran	v
Important In	nformation:							2000
				G. REPORTER 1. Name and Add		dentiality s	section on b	ack)
C. PRODUCT A Product Available f	VAILABILITY or Evaluation? (Do not sen	d product to FDA)		Name: (b) (6)				
	Returned to Manufact	urer on	n/dd/yyyy)	Address: (b) (f				(b) (6)
D. SUSPECT P	RODUCT(S)	1min	, surj / / / /	city: (b) (6)			State: (6) (6) ZI	P (D) (O)
	Manufacturer (from product	t label)		Phone # 9285335079			mail ::ose40@q.c	rom
#1 Name: Kerati								
#1 Name: Kerat.1 Strength: Manufacturer 8: #2 Name:	zave			2. Health Profess		upation	4	Also Reported to:

546681

B.5. Describe Event or Problem (continued)

... put lotion on all parts i could reach and went to bed. The next day all was worse. I put Benadryl lotion on my back with some relief. My face was dry and scaly so I used a face cream. I tried, Benadryl lotion, Aloe sunburn gel and cream and nothing stopped the burning on my neck. I went to the doctor at 145 (Thursday) and she gave me some for immediate use and a prescription for more. She told me to use Benadryl cream and pills for the itching.

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

Form Approved: OMB	No. 0910-029	1. Expires:	12/31/201
	See OMB	statement	on reverse

Triage unit sequence #

A. PATIENT IN			1	The second second	Dose or Amount	Freque		
Patient Identifier b) (6)	Age at Time of Event or Date of Birth:	3 Sex	4. Weight	#1	Prednisone	Once	daily Take	n by mouth
In confidence		Male	kg kg			4 4		
B. ADVERSE E Check all that apply: . Adverse Event	EVENT, PRODUCT PRO				tes of Use (if unknow best estimate)	n, give duration	Sto	vent Abated After Use pped or Dose Reduced? Yes No Doe App
Product Use E	rror Problem with Differe	nt Manufacturer	of Same Medicine				#2	Tyes TNo TDo
(Check all that app	Disa	bility or Permanent			gnosis or Reason for Lichen planiplac		8. E	vent Reappeared After leintroduction?
The second secon	g ☐ Cong - initial or prolonged ☐ Othe vention to Prevent Permanent	the state of the s	nt Medical Events)	6. Lot #1	#	7. Expiration	Date	Yes No Do
3. Date of Event (mr	The state of the s	e of this Report	T. Wardalfan	#2		#2		ar a ainque is
06/10/2013		18/2014	minual yyyy)	E. \$	SUSPECT MEDI	CAL DEVIC	E	
5. Describe Event, F In 2013 summ	Problem or Product Use Erroter I was going to van I did keratin ha	r isit my coun		1. Bra	ind Name			V-71
land, tx and see dermatol safe to do o Doctor preso	saloon called beauty before doing kerati ogist first just to or not since I was h oribed me one tube a of the treatment The	n treatment ask him tha aving some d nd said you	I went to t is it ry skin too can go		mmon Device Name nufacturer Name, C		APR	2 2014
after three dermatologis	onth if treaement my months when I came at and he gave me tr cooking at me	back to DSA	I see the	4. Mo	del#	Lot#		5. Operator of Dev
				Cat	talog #	Expiration	Date (mm/dd/y	(yyy) ☐ Lay User/Patien
Relevant Tests/La	aboratory Data, Including Da	ites		Sei	rial#	Other#		- Agino
ovin probal	on narch			2 161	nplanted, Give Date	Vision Add Section	To the French water	d, Give Date (mm/dd/vy
				8. Is t	A Marie Constitution	3,610		d Reused on a Patient?
		March Th		9. If Y	es to Item No. 8, Ente	r Name and Add	Iress of Reproce	ssor
	istory, Including Preexisting gnancy, smoking and alcohol ditions:				THER (CONCO			
Important In	ntormation:			G. R	EPORTER (See	confidentia	lity section o	n back)
C. PRODUCT A	VAILABILITY or Evaluation? (Do not send	product to FDA)		1. Na Na	me and Address me: (b) (6) dress: (b) (6)			
Yes No	Returned to Manufacture	er on:(mn	rvda/yyyy)		4000			715. 22.44
1 Name: Kerati	Manufacturer (from product la	ibel)		Phon (b) (6			E-mail (b) (6)	2IP 77479
Strength: Copal Manufacturer:	11a				alth Professional?	3. Occupation		4. Also Reported to:
2 Name: Strength: Manufacturer				5. If y	ou do NOT want your			User Facility Distributor/Impo

FORM FDA 3500 (1/09)

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

547413

B.5. Describe Event or Problem (continued)

... forhead I realized my hair line is going up receding hairline and my hair can be easily pop out with roots Then I change me doc she did my biopsy which states scarring alopecia lichen pilanpolaris at its significant stage I am loosing my hair like crazy with roots and doc said hair won't come back since there is no follicles All of this is because of keratin treatment

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 175942.

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

Sincerely yours,

Debra G. Street

Debra Street

Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Enclosure

Incident Details

Document | 1440557A

Number:

Report Number: 20140430-43443-2147444968

Report 4/30/2014

Submitted Date:

Who You Are: Consumer

Incident I have been using suave products exclusively for about 10 years and have never had something

Description: like this happen.

About 3 weeks ago I purchased the "keratin infusion heat defense leave in conditioner" for my hair. I was looking for something new. It worked great on my hair, and I loved it! A few weeks later I bought the matching shampoo and conditioner "natural infusion with awapuhi, ginger, and honeysuckle"

I used all three the first day, and noticed the conditioner made my hair smell like perming solution (which was weird) but I styled my hair as usual and went to work. Later, I noticed some of my hair was lighter in color, sort of golden... But brushed it off.

It was Probably the third or 4th day I used all three products, I started to style my hair as usual, and chunks of hair started coming out of my head. The chunks look like they had been melted, and were all different lengths. One chunk fell in my hand, and when I touched it the hair turned to dust. Around my face I could see my hair was broken to about an inch in length.

That day I noticed it looked like I had white hair, but it was the golden, damaged hair... Like tinsel in my dark brown.

The next day I shampooed with my regular suave shampoo and my hair started falling out in the shower. I really thought it was all going to come out and I was going to be bald. Huge wads of hair, over and over . I showed until they were all out and went to work. I looked awful.

Later that day I went to the salon, and she said it looked like something had "eaten" my hair. It was all different lengths and badly damaged. She cut about four inches off (just straight)and I purchased some high quality shampoo and conditioner. I cannot style it for fear of more breakage and it looks horrible.

Incident Date: 4/16/2014

Incident Home/Apartment/Condominium -(b) (6) United States This

Location: is my home address

Victim Details

First Name (b) (6) Last Name: (b) (6)

CAERS 05/02/2014

Injury Incident, No Injury

Information:

Victim is of No Hispanic/Latino

oriain?

Race: White

Other

Race/Ethnicity:

My Relationship Self

to Victim:

Gender: Female Age when 34 Years

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

incident occurred:

, United States Address: (b) (6)

E-mail: (b) (6)

Phone Number: (b) (6)

Product Details

Product The first product I used was Suave "keratin infusion heat defense leave in conditioner" A few Description: weeks later I bought the matching shampoo and conditioner "natural infusion with awapuhi,

ginger, and honeysuckle" listed as anti-breakage shampoo and conditioner.

Product Shampoo and Conditioner

Category:

Product Type:

Brand Name: Suave

Manufacturer / Unilever

Importer / Private Labeler

Name:

Model Name or 83223367, 83223359, 83176479

Number:

Serial Number: 01134JU36, 01044JU36

Date Manufactured:

Manufacturer Date Code:

Manufacturer Not specified

Address:

Manufacturer Website URL: Manufacturer Phone Number:

Retailer: Walmart Retailer State: Lansing, MI

Additional Details

Purchase Date: 4/12/2014 This date is an estimate

I still have the Yes product in my possession.

The product N/A was damaged before the incident.

The product N/A was modified before the incident.

Have you Yes contacted the manufacturer?

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If not, do you N/A plan to contact them?

Explanation: I still have all three products. I have contacted Suave, and "they are sorry and investigating" but we are playing phone tag. They would like me to send the unused product for testing.

```
Your Contact Information
     First Name: (b) (6)
      Last Name: (b) (6)
        Address: (b) (6)
                                                             , United States
           E-mail (b) (6)
  Phone Number: (b) (6)
    Consent
  May we include No, do not include my Report on SaferProducts.gov.
     your Report,
    including any
   documents or
    photographs
    that you have
      attached to
     your Report,
     but without
  your name and
          contact
  information, in
    CPSC's Public
       Database?
  May we release Yes, you may release my name and contact information to the product manufacturer /importer /
  your name and private labeler.
          contact
   information to
     the product
  manufacturer /
       importer /
   private labeler
     identified in
    your Report?
   I certify that I Yes
   have reviewed
  the Report and
         that the
     information
  provided in this
    Report is true
  and accurate to
  the best of my
     knowledge.
     information,
       and belief.
OMB Control Number 3041-0146
```

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

Unilever Home & Personal Care USA (Division of Conopco, Inc.) 920 Sylvan Ave. Englewood Cliffs, New Jersey 07632-3313

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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, Libra 4. Street

Debra Street Chief

Emergency Response and Surveillance Branch

Center for Food Safety and Applied Nutrition

Enclosure

MEDWATCH

The FDA Safety Information and



Internet Consumer Report

Triage unit sequence #

For VOLUNTARY reporting of adverse events, product problems and product use errors Form Approved: DMB No. 0910-0291, Expires: 12/31/2011 See DMB statement on reverse.

A. PATIENT IN		12 Car	4. Weight	2. D	ose or Amount	Frequer	ncy Route	
(b) (6)	Age at Time of Event or Date of Birth: Years (b) (6)	3. Sex Female Male	140 lb	#2				
Check all that apply:	EVENT, PRODUCT PR		RROR	(or	es of Use (If unknows best estimate) /29/2014 -	n, give duration,	Stoppe	nt Abated After Use ed or Dose Reduced? Yes No Doe
Adverse Even Product Use E	t Product Problem (e.		The state of the s	#2				Yes No Doe
(Check all that app	Disa	bility or Permanent genital Anomaly/Bir			gnosis or Reason fo traighten hair	r Use (Indicatio	8, Ever Rein #1	nt Reappeared After troduction? Yes No Doe App
The second secon	- initial or prolonged Othe vention to Prevent Permanent			6. Lot #1	#	7. Expiration #1	Date	Yes No Doe App
3. Date of Event (mi		te of this Report (r	mm/dd/yyyy)	#2 E. S	USPECT MEDIC	#2 CAL DEVICE	B	
and the second state of the second of	Problem or Product Use Erro	or	dahuda anlu	1. Bra	nd Name		870	
affects the	hairdresser. I have I'm nauseous all th	now been si	ck for a	2 Cor	nmon Device Name		CIU	
headaches, i	fatigue after 3 hour at all, I feel mise	s of movemen	t and have	2. 001	minori Device Hame		MAY - 7 2	014
is so health organic and	ny. I don't smoke or gluten free most of oga regularly.	drink at al	1. I eat	3. Mar	nufacturer Name, Cit	y and State		
				4. Mod	del #	Lot#		5. Operator of Dev
				Cat	alog#	Expiration	Date (mm/dd/yyyy	Lay User/Patien
	aboratory Data, Including Da e dr on Thursday.	ntes		Ser	ial#	Other#		
				6. If In	planted, Give Date	(mm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yyy
					nis a Single-use Dev Yes \(\subseteq No	ice that was R	eprocessed and R	eused on a Patient?
7 0% - 10 - 100			-6-2	9, If Yo	es to Item No. 8, Enter	Name and Add	ress of Reprocesso	r
allergies, race, pre Race:White	istory, Including Preexisting agnancy, smoking and alcohol and information see	use, liver/kidney pr			THER (CONCON			
	or Evaluation? (Do not send)	Medicinal Supply	======	1. Nan Nar	EPORTER (See ne and Address ne: (h) (6) (6)	confidential	ity section on l	oack)
	Returned to Manufacture	er on(mn	n/ad/yyyy)	City	(b) (6)		State - 7	ge: (b) (6)
#1 Name: Formal	Manufacturer (from product la	ibel)		Phone	Particular Comments		(b) (6)	
Manufacturer: 2 Name:	result reviews				tth Professional? 3			4. Also Reported to: Manufacturer User Facility
Strength: Manufacturer:					ou do NOT want your i ne manufacturer, plac			Distributor/Impo

FORM FDA 3500 (1/09)

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

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

Medical Conditions: None Allergies: Seasonal

Important Information: None

RX Meds: Bupropion, Lamotrigene, trinessa

OTC Meds: Glucosamine

CASAK

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Triage unit sequence #	549495
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A. PATIENT	INFORMATION			-	2. Dose or Amo	ount	Frequency	Route	
1. Patient Identifie (b) (6)	2. Age at Time of Date of Birth:	Event or	3. Sex	4. Weight	#1			4-	
(b) (d)	27 Years	400	√ Female	153 _{lb}	#2				
	(b) (6)		☐ Male	or kg	"2				
In confidence B. ADVERSE Check all that apply	EVENT, PROD	UCT PRO	DBLEM OR E	RROR	3. Dates of Use (III (or best estimate	e)	duration) from/to	Stoppe	t Abated After Use d or Dose Reduced?
Adverse Eve	ent Product P	roblem (e.g	g., defects/malfund	ctions)	#1 04/25/2014	17		#1 📋	Yes No Do
	Error Problem v	0.556.50	nt Manufacturer	of Same Medicine		same for the N	n all a a bland l	#2 🔲	Yes No Do
2. Outcomes Attr (Check all that a	ibuted to Adverse E		bility or Permanent	Damage	4. Diagnosis or Ro #1 Straighten	the state of the s	ndication)	Reint	Ap t Reappeared After troduction?
Life-threaten	(mm/dd/yyyy)	□ Conn	enital Anomaly/Bi	th Defect	#2			#1 🔲	res No Do
_	on - initial or prolonge		Charles of the constant		6. Lot #	7. Ex	oiration Date	#2 🔲	res No Do
	ervention to Prevent F				#1	#1	Canada and and	9. NDC	# or Unique ID
3. Date of Event (mm/dd/yyyy)	4. Date	e of this Report (mm/dd/yyyy)	#2	#2		100	
04/25/201	4	05/	07/2014		E. SUSPECT	MEDICAL D	EVICE	10000	
Used a ker	t, Problem or Produc atin hair smoo nued to have b hairline	thing tr	eatment 2we		Brand Name Common Device	e Name			CTU
					3. Manufacturer N	lame, City and S	itate	M.	CTU AY = 8 2014
					4. Model#	Lot	1#		5. Operator of De
					Catalog #	Ex	piration Date (m	m/dd/yyyy)	Lay User/Patie
Relevant Tests	/Laboratory Data, In	cluding Dal	tes		Serial #	Ott	ner#		
					6. If Implanted, Gi	ve Date (mm/dd	уууу) 7. If Ex	planted, G	ive Date (mm/dd/yy
					8. Is this a Single- Yes No		was Reprocess	sed and Re	eused on a Patient?
Other Relevant	History, Including P	reexisting	Medical Condition	ns (e.g.,	9. If Yes to Item No	. 8, Enter Name a	ind Address of R	eprocessor	3. 1
Race: Black	pregnancy, smoking a /African Ameri	can		roblems, etc.)	F. OTHER (CO	Control of the Contro			
ror additi	onal informati	on see i	s/ below.			is increpy date.	Taxaaa baaan	, or over	,
					G. REPORTER	A STATE OF THE REAL PROPERTY.	lentiality sect	tion on b	ack)
Product Available	AVAILABILITY for Evaluation? (Do	STATE STATE	economic actions		Name: (b) (6) Address: (b) (6)				
Yes No		fanufacture	r on:(mn	n/dd/yyyy)	City: Kingspo	ort	Str	ate: TN ZI	P: 37664
	PRODUCT(S) 1, Manufacturer (from	n product lat	bell		Phone #		E-mail	1000	
1 Name kerat Strength smo	in treatments oth and shine						(b) (6)		
Manufacturer					2. Health Professi	5000	oation	4	. Also Reported to:
2 Name: Strength:					Yes No		disclosed		Manufacturer User Facility
					5. If you do NOT w	ant your identity	uisclosed		1-1

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

OTC Meds: B12

The FDA Safety Information and

Triage unit sequence #

Internet Consumer Report 75

For	VOLUNTARY reporting	of
adverse	events, product problem	s and
	product use errors	113

Form Approved:	OMB	No.	0910-0291	Expires:	12/31/2011
A WILLIAM STATE OF			See OMB s	talement	on reverse.

	Reporting Progra	ui .						
A. PATIENT IN		ot or 13 See	4. Weight	2. Dos	se or Amount	Frequer	icy Route	
wis	2. Age at Time of Eve Date of Birth:	A CONTRACTOR OF THE PARTY OF TH	4. Weight					
	43 Years	✓ Female	105 16	#2 [
la secretar		☐ Male	or kg					
In confidence	EVENT PRODUC	T PROBLEM OR E		3 Dates	of Use (If unknown,	give duration	from/to 5 Even	nt Abated After Use
heck all that apply:	LVENT, PRODUC	T PRODUCE OR E	KKOK	(or be.	st estimate)	give darandrij		d or Dose Reduced?
Adverse Even	t Product Prob	lem (e.g., defects/malfun	ctions)	#1			#1 🔲	Yes ✓ No □ Doe App
Product Use E		Different Manufacturer		#2	The street		#2 🗔	Yes No Doe
	uted to Adverse Event			The second second	osis or Reason for		n)	App
(Check all that ep	ply)	7 Disability on B	I Damas	#1 Hai	ir conditioning	treatment		t Reappeared After troduction?
Death:	mm/dd/yyyy)	Disability or Permanen	Darnage	#2			#1	Yes No Doe
Life-threatenin	g [Congenital Anomaly/Bi	rth Defect				#0 D	
The second second	- initial or prolonged	- Trail of Trail Continued Spring and St	The Comment of the same	6. Lot#		7. Expiration #1	-	App
Required Inter	vention to Prevent Perm	nament Impairment/Dama	ge (Devices)	1000		7.1	9. NDC	# or Unique ID
Date of Event (m	The state of the s	4. Date of this Report (mm/dd/yyyy)	#2		#2		
05/16/2014		05/18/2014		Section 2 Section 2	SPECT MEDIC	AL DEVICE		
	Problem or Product Us			1. Brand	Name			
		g" treatment on E catin was GK / G1		1.0				
Keratin. I d	do not know of a	specific formul	ation, My	2. Comm	non Device Name			(Serve
		ne keratin applie etologist used a		1				CN
		etologist used a n. When the appli		7 18	facturer Name, City	and Stat-	227	• 16
complete, I	sat for about 5	minutes, then s	he used a	3. Manu	racturer warne, City	and State	MA	Y 1 9 2014
		She then used a hot Iron portic						- see a tab
treatment, 1	I felt my scalp	tingling but it	did not	4. Model	1#	Lot#		5. Operator of Devi
	icant at the time my scalp began .	me. About 24 hour	s after the	4. Model	1#	Lot #		Health Professio
erea encere,	my scorp segun .							realth riblessio
				Catalo	og #	Expiration	Date (mm/dd/yyyy,	Lay User/Patient
				Lan		100		Other:
. Relevant Tests/L	aboratory Data, Includ	ling Dates		Serial	#	Other#		
				200				
			4.0	g if invest	lanted, Give Date (r	mm/dei/mand	7 If Explanted	Give Date (mm/dd/yyy
			4.51	Q. ii iiiipi	anteu, Give Date (f	muuwyyyy)	7. ii Explainted, C	one Date (minutaryyy,
						e that was Re	processed and Re	eused on a Patient?
					es No			
				9. If Yes	to Item No. 8, Enter I	Name and Addr	ess of Reprocesso	
Other Relevant H	listory, Including Pree:	xisting Medical Condition	ons (e.g.,					
allergies, race, pre Race: White	egriancy, smoking and a	alcohol use, liver/kidney p	robiems, etc.)	E 031	IED (CONOCH	TANE NE	DICAL PROF	ICTC .
		Contract to the second	4.1		HER (CONCOM names and therapy			
For addition	nal information	see B7 below.		Froduct	names and therapy	dates (exclud	e treatment of ever	ni)
				G. REF	PORTER (See c	onfidentiali	ty section on b	ack)
PRODUCT	AVAILABILITY	~ * -	- 2		and Address			
the Real Property and the Control of	for Evaluation? (Do not	t send product to FDA		100000000000000000000000000000000000000	(b) (6)			
	Returned to Manu			Madre	ss; (b) (6)			
			n/dd/yyyy)	01000	. Street		A-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1	In the law
. SUSPECT P			100	City (CONTRACTOR OF THE PERSON OF TH		State Min Z	(b) (d)
	Manufacturer (from pro	aduct label)		Phone # (b) (6)			E-mail (b) (6)	
Name: Global Strength:	Keratin			(0) (0)			(0)(0)	1 7 7 7
Manufacturer				2. Health	Professional? 3.	Occupation	14	Also Reported to:
Name:				□ Y	es No			Manufacturer
Strength:			1.1		do NOT want your id			User Facility
Manufacturer				to the	manufacturer, place	an "X" in this i	pox:	☐ Distributor/Impor
ODER FOR SPA	0 (4 (00)	the the top of the state of the state of	at 135 attenta da ada	Market M. C.	A STATE OF THE STA	- influence in the contract of	200000000000000000000000000000000000000	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

550620

B.5. Describe Event or Problem (continued)

... itching and burning. I could feel inflammation of my scalp — in small bumps and in large raised/swollen patches. At about 30 hours after treatment, I began to notice red raised bumps along my hairline (around my face). As soon as I returned home, I washed my hair and face repeatedly to remove the chemicals. I took a Benadryl, which seems to have helped somewhat with the itching and inflation. It is now just about 50 hours after treatment and my scalp still itches and burns. (Treatment was done at Spencer Malay Salon in Atlanta, GA)

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

Medical Conditions: None Allergies: None Important Information: Non-smoker, no health problems RX Meds: Lexapro

OTC Meds: Multi-vitamin, calcium supplement

Global Keratin Corp 5555 Ravenswood Rd, Ste 16B Fort Lauderdale, Florida 33312

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 176596.

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,

Ted Elkin Director

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

For VOLUNTARY reporting of adverse events, product problems and

Form Approved	CIMB ING	Na in-nsa	I Expires.	12/2/12/1
		See OMB	statement	on reverse

	t Reporting Pro	F-0 1		_	M.		Devide:	
	er 2. Age at Time of Date of Birth:		3. Sex	4. Weight	#1 Dose or Amou	rit Freque	ncy Route	
In confidence	61 Years (b)(6)		☐ Male	or kg	#2			
110.00	E EVENT, PROD	UCT PRO	BLEM OR E	RROR	(or best estimate)	inknown, give duration,	Stoppe	nt Abated After Use ed or Dose Reduced?
. Adverse Ev			., defects/maltunc at Manufacturer o		#1 about 1 mon #2	th		Yes No Dos
Outcomes Atti	ributed to Adverse E apply)		ility or Permanent	Damage	#1 Temporarily Erizzy heir	sson for Use (Indication straighten curly	8. Ever Rein	Yes No Applet Reappeared After troduction?
Life-threater	(mm/dd/yyyy) ning ion - initial or prolonge		enital Anomaly/Bir		#2 6. Lot #	7, Expiration		Yes No Doc
The second secon	tervention to Prevent	Permanent Ir	mpairment/Damag	e (Devices)	#1	#1	9. NDC	# or Unique ID
3. Date of Event 05/16/201		and the second second	of this Report (r 04/2014	mm/dd/yyyy)		MEDICAL DEVIC	E	
I am a 62	nt, Problem or Produ year old white	female	who was born	n with	1. Brand Name			
thick curly, frizzy hair. I purchased Tresemme's Keratin Smooth 7-Day Smooth System from my local Target Store and used it as per the package directions for about a month. Soon my hair began to noticeably		2. Common Device Name						
	I get my hair very alarmed lenced.				3. Manufacturer Na	me, City and State	JL	IN - 5 2014
					4. Model #	Lot#		5. Operator of Dev
					Catalog #	Expiration	Date (mm/dd/yyyy	Lay User/Patie
	s/Laboratory Data, Ir ood lab	ncluding Dal	es		Serial #	Other#		
					6. If Implanted, Giv	e Date (mm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yy
					8. Is this a Single-u	se Device that was R	eprocessed and R	eused on a Patient?
20. 2					9. If Yes to Item No.	8, Enter Name and Add	ress of Reprocesso	r
allergies, race, Race: White	t History, Including pregnancy, smolong e	and alcohol u	medical Conditio ise, liver/kidney pr	ns (e.g., roblems, etc.)	F. OTHER (CO	NCOMITANT) ME	EDICAL PROD	UCTS
For additi	ional informat	ion see A	37 below.		Product names and	l therapy dates (exclu	de treatment of eve	nt)
					G. REPORTER	(See confidential	lity section on l	back)
roduct Availab	T AVAILABILITY le for Evaluation? (E	o not send p	A comment of the state of the s	20	Name (b) (6) 1 Address (b) (6)			
	PRODUCT(S)	Manufacture	r on: (mn	n/dd/yyyy)	City: (b) (6)		State; Mile 2	(P: (b) (6)
Name, Strengt	th, Manufacturer (fro				Phone # (b) (6)		E-mail (b) (6)	-
Strength: Manufacturer	tin Smooth 7-1	ay Smoot	h Syst			nal? 3. Occupation		4. Also Reported to
2 Name: Strength					Yes No	nt your identity disclos	od	✓ Manufacturer User Facility
Manufacturer:					to the manufactur	er, place an "X" in this	box:	Distributor/Imp

552932

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

... work indicate my hormone levels are at pre-menopausal stage (I had a hysterectomy at 40). One thyroid indicator was also puzzling leaving my doctor to recommend retest in 6 weeks. I have also been experiencing long bouts with nausia and digestive discomfort.

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

Medical Conditions: High blood presence

Allergies! Name

Important Information: Non-smoker, non-drinker, no street drugs

RX Meds: Micardis 80, Bystolic

OTC Meds: Multiple vitamin, Olive leaf extract, Red yeast rice, Sam-E (400 mg), Ester-C (500 mg), Glucosamine/Chrondrhitin (Advanced Formula), Biolin

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 176963.

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,

Ted Elkin Director

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure

[Close]

FACTS Interface

FACTS Complaint #134206 (CAERS #	¥177161)		
Complaint Date	09/17/2013	Complaint Source	Consumer
Accomplishing District	FLA-DO	Complaint Status	Archived
How Received	Telephone		

Name	(b) (6)	Work Phone	
Address	(b) (6)	Home Phone	(b) (6)
		Source POC Name	
City	(b) (6)	Source Phone	
State	(0) (9)		
Zíp	(b) (6)		
Province			
Country	US		
Mail Code			

Complaint / Injury

Complaint Description

Complaint visited her hair salon on 9/16/2013 for a Smoothing Therapy Keratin complex hair treatment. Complainant states product used to be Coppola Keratin treatment which she states contained formaldehyde, but is now just Smoothing Therapy Keratin Complex. Before product was applied, complainant questioned her hairdresser as to whether or not the product contained formaldehyde. The hairdresser gave the bottle to complainant to read the ingredients and no formaldehyde was listed. As soon as the product was applied both the hairdresser and complainant experienced burning/stinging eyes. The smoothing process takes 3 hours and then the hair is flat ironed. Complainant states that w/in 30 minutes of the ironing process, she began to feel nauseous and faint due to the fumes expelled during the ironing process. She was pale & colorless; her lips were white. She stepped outside for a few minutes and states she could actually see smoke emitting from her hair from the treatment and flatironing. After resuming the flatironing, her symptoms worsened. When she returned home, she experienced nausea, vomiting, diarrhea (once), tremors and shakiness, disorientation. Complainants boyfriend arrived and called Poison Control. PC advised complainant to use her inhaler. (complainant has confirmed allergy to shrimp, dustmites and cats). She is a nurse and was unable to go to work today. Complainant states she slept through the night; but is still experiencing nausea & shakiness. She also has a hive on the side of her face.. This is the first time complainant has had the Keratin treatment. The hairdresser states she has applied this treatment multiple times and has never seen a reaction like this.

Adverse Event Result	Non-serious Injuries/ Illness
Adverse Event Date	9/16/2013
Notify EIO/EMOPS?	Yes
Notification Date	09/17/2013
Attended Health Professional?	No
Required Hospitalization?	No
Emergency Room/ Outpatient Visit?	No
Reported Complaint To?	Other
Reported Complaint 10?	Other

Need Additional/ FDA Contact?

Remarks

Complaint contacted Poison Control; Copomon Enterprises 888-409-4445. Complainant was given Keratin Care Shampoo and Conditioner by hairdresser for follow-up use after treatment. From www.petercoppola.com website: Rewind the strands of time with the new Coppola Keratin Treatment, Keratin and Ceramide, Formaldehyde-Free and Aldehyde-Free Treatment. This versatile treatment doesn?t just smooth hair; it safely provides the ultimate anti-aging boost, adds volume and restores hairs youthful look and texture for a minimum of 3 months. The sophisticated formula uses the highest quality ingredients combined with a low pH mechanism to soften and smooth every hair type without the concern of harmful chemicals. Infused with vital Keratin amino acids and damage-reversing Ceramides. The new Coppola Keratin Treatment is part of the Peter Coppola Keratin Concept collection. Features: ?Adds volume and restores hairs youthful look and texture. ?Provides the ultimate anti-aging boost ?Infused with vital Keratin amino acids and damage-reversing Ceramides. ?Reduces frizz up to 95%. ?100% true Formaldehyde-Free and Aldehyde-Free system ?Leaves hair full-bodied and frizz free for up to 3 months.

Complaint Symptoms

000001

Symptom Name	Duration	Remarks
Hives (urticaria, welts)	null null	one hive on side of face
Eye irritation	null Hour(s)	Burning/stinging of eyes
Vomiting	null Hour(s)	multiple times; improved
Nausea	null null	
Changes in skin and nail coloration (cyanosis, flushing)	null Hour(s)	Pale, colorless; lips were white
NEC - Identify in Remarks	null null	tremors; shakiness
Diarrhea	null Minute(s)	1X

Health Care Professional

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

20000000		
Coppola		
Keratin Complex Smoothing Therapy		
53ED03	Qty/Unit	
	Package	
	Lot/Serial	
No	Purchase Date	
	Amount Consumed/Used	
	Date Discontinued	
	Imported Product?	No
	Label Remarks	
	Keratin Comple 53ED03	Keratin Complex Smoothing Therapy 53ED03 Qty/Unit Package Lot/Serial No Purchase Date Amount Consumed/Used Date Discontinued Imported Product?

Manufacture	Manufacturer/Distributor		
FEI	Name & Address	Home District	Firm Type
3006524310	Copomon Enterprises, LLC 7700 Congress Ave Ste 2201 Boca Raton FL 33487-1361	FLA-DO	Manufacturer

Initial Evaluation / Initial Disposition

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

Disposition Date 09/17/2013

Remarks

No product information available. Complainant did not want to provide name or contact information for salon or hairdresser. Manufacturing information provided by Alexia Customer Service Rep. 888-409-4445. Keratin Complex. Alexia stated she is not aware of any similar complaints: she also affirmed that the Keratin treatment does not contain formaldehyde. No inspectional history for FEI. Forwarded to FLA-DO; unable to forward to NJ State for follow-up as no salon information available.

Problem Keyword	Problem Keyword Details		
Reaction	nausea, vomiting, diarrhea, burning/stinging eyes, disorientation, lightheadedness, tremors,		

Cosmetic				
Cosmetic ID (b) (6)				
DOB		Age		
Gender	Female	Race	Question Not Asked	
Application Place	Salon/SPA	Reason for Use	Hair Preparations (Non-Coloring)	
Application Site	Scalp	Other Products?	No	
Directions				
Directions Followed?	Yes	Product Duration		
Frequency of Use	Other	Reaction Site	Other	
Product Use in Off-Label Manner?	No	Off-Label Manner Desc		
Warning Statement on Label?		Warning Statements?		
Preexisting Conditions?	Yes	Treatment	Self -Medicated	
Current Status	Improved			
Medical Diagnosis		Medical Treatment		

000002

Remarks

First use of product; complainant has allergies to shrimp, dustmites, cats; complainant administered inhaler

Adverse Events

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

[Close]

Copomon Enterprises, LLC 7700 Congress Ave Ste 2201 Boca Raton, Florida 33487-1361

To Whom It May Concern:

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

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To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 177161.

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,

Ted Elkin Director

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Enclosure



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

EDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Check all that apply

EASE TYPE OR USE

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

For VOLUNTARY adverse events, pro product

he FDA Safety	Information and	adverse es		uct problems and se errors	Triage unit sequence #	5547	23
A. PATIENT II Patient Identifier	Reporting Program VFORMATION 2. Age at Time of Event or Date of Birth: 25. Years (b) (6)	3. Sex 4.	Weight 125 _{1b} kg	2. Dose or Amount	t Frequ	ency Route	
In confidence B. ADVERSE heck all that apply:	EVENT, PRODUCT PR	OBLEM OR ERRO		3. Dates of Use (If uni (or best estimate)	known, give duration		nt Abated After Use ed or Dose Reduced?
Adverse Even	it Product Problem (e Error Problem with Differ	g., defects/malfunctions, ent Manufacturer of Sar		#1 #2		#2 🗆	Yes No Does
. Outcomes Attributed to Adverse Event. (Check all that apply) ☐ Death: ☐ Death: ☐ Disability or Permanent Damage (mm/dd/yyyy) ☐ Life-threatening ☐ Congenital Anomaly/Birth Defect			#1 #2		8. Ever Rein	Apply nt Reappeared After ntroduction? Yes No Does Apply	
Hospitalization	n - initial or prolonged 🗸 Othe vention to Prevent Permanent	er Serious (Important Med	dical Events)	6. Lot# #1	7. Expiratio		Yes No Does Apply
. Date of Event (m	CONTRACTOR	te of this Report (mm/de	d/yyyy)	#2 E. SUSPECT M	#2 EDICAL DEVIC	E	
Describe Event, Problem or Product Use Error My salon has been using the Brazilian Blowout Product for a couple years. After all the complaints a couple years ago, we were informed by the employer that the product was safe and the level of formaldehyde was within the FDAs "safe" levels. We have no ventilation			Brand Name Common Device N	ame		CTU	
system in the salon, even after repeatedly asking for one. I am still required to do the service and I have been having to do about one a week for the past two months. Normally, I experience burning, watering eyes, blurred vision, sore throat, loss of taste/smell afterwards, migraines, nausea, and chest discomfort. I have been sick		3. Manufacturer Name, City and State JUN 2 3 2014					
		4. Model #	Lot#		5. Operator of Device Health Profession		
				Catalog #	Expiratio	n Date (mm/dd/yyyy	Lay User/Patient
Relevant Tests/L	aboratory Data, Including D	ates		Serial #	Other#		
				6. If Implanted, Give I	Date (mm/dd/yyyy)	7. If Explanted,	Give Date (imm/dd/yyyy)
				8. Is this a Single-use Yes No 9. If Yes to Item No. 8,			
Other Relevant H allergies, race, pro Race: White	listory, Including Preexisting egnancy, smoking and alcohol	g Medical Conditions (e. use, liver/kidney problem	g., ns, etc.)	F. OTHER (CON	COMITANT) M	EDICAL PROD	ucts
				riodadi nama ana a	nerapy dates (exch	ove treatment of eve	nay
	AVAILABILITY for Evaluation? (Do not send	* SOME TOTAL STATE OF		f. REPORTER (S 1. Name and Address Name:(b) (6) Address: (b) (6)		lity section on l	back)
. SUSPECT P		(mm/dd/y)	yyy)	City: Wyomissin	1	State: PA Z	SP: 19610
Name Brazil	Manufacturer (from product) ian Blowout ilian Blowout	abel)		Phone #		E-mail (b) (6)	
Manufacturer;	ALLEN DAVINAV			2. Health Professiona Yes No	3. Occupation		4. Also Reported to: Manufacturer
Strength:				5. If you do NOT want s	your identity disclos	haz	User Facility

FORM FDA 3500 (1/09)

Manufacturer:

#2 Name.

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

5. If you do NOT want your identity disclosed

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

Distributor/Importer

B.5. Describe Event or Problem (continued)

... and put on antibiotics for throat/chest infections more in the past year alone more than in the past ten years combined. After the most recent treatment, last Wednesday, I had chest pain, chest tightness, shortness of breath, and labored breathing constantly. It has been almost five days. I have an appointment with the doctor tomorrow morning. It has prevented me from doing normal daily activities for five days. I have no prior medical concerns involving lung function, asthma, allergies, or fatigue. I cannot understand how hair stylists are still having to be subjected to this torture! When is the FDA going to step in and stop the release of this poison to salons? Even with a doctors note for me to be excused from performing the service, I still have to be in the salon while others perform the service. The one I did on Wednesday sent a co-worker in her 60's to the bathroom vomiting. It's hurting all of us. We have had enough of this company jumping through loop-holes, it needs to be banned. Before someone gets permanent medical damage. Thank you.

[Close]

FACTS Interface

FACTS Complaint #137637 (CAERS #	177818)		
Complaint Date	07/09/2014	Complaint Source	Consumer
Accomplishing District	LOS-DO	Complaint Status	Archived
How Received	Telephone		

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

Complaint / Injury

Complaint Description

Complainant reports having three "Brazilian Blowout" services (hair straightening treatments) done at a salon over 12 months (most recent service received on April 23, 2014). She alleges noticing her hair falling out and thinning in early May (clarifies that no balding/bald spots occurred). She initially believed her thinning hair was due to stress but now suspects this salon product is the cause because she learned of formaldehyde in the product through reports found on the internet. She reports discussing her concerns with the salon owner and states that the salon owner advised her that the product was reformulated and no longer contains formaldehyde. She also reports that when initially inquiring about the product, the salon owner advised her that she was the only one of 300 clients who received this service to complain about the product. Complainant called her Dermatologist the week of 06/30/2014 and was advised to take biotin to promote hair health. Dermatologist: Dr. Mark Liska, 37 Edgerton Drive, North Falmouth, MA 02556 (508-563-2550). Complainant requested information on any previous complaints about this product. Advised of FOIA and given FDA website information on FOIA requests. Complainant concerned about receiving closure for her specific complaint. She wishes to be advised of complaint outcome. She was provided with ACIL and ASTM private lab contact information should independent analysis of product be desired.

Adverse Event Result	Non-serious Injuries/ Illness
Adverse Event Date	05/2014
Notify EIO/EMOPS?	Yes
Notification Date	07/09/2014
Attended Health Professional?	No
Required Hospitalization?	No
Emergency Room/ Outpatient Visit?	No
Reported Complaint To?	Other

Need Additional/
FDA Contact?

Unknown

Remarks

Complainant reported thinning hair to salon. Photos of product provided.

Complaint Symptoms					
Symptom Name	Duration	Remarks			
Other Change in hair or nails, not listed	null null	Thinning hair, losing hair			

Health Care Professional

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

Product and Labeling			
Brand Name	Brazilian Blowout		
Product Name	Acai Professional	Smoothing Solution	
FDA Product Code	53ED03	Qty/Unit	34 Ounces
UPC Code	Unknown	Package	Bottle
A CONTRACTOR OF THE PROPERTY O		72773	000001

Exp/Use By Date	Unknown	Lot/Serial	7348131B5
Product Used?	Yes	Purchase Date	05/2014
Date Used?	05/2014	Amount Consumed/Used	"3 pumps"
Amount Remained	Unknown	Date Discontinued	05/2014
Country of Origin		Imported Product?	No
Retailer Name	Creative Cuts	Label Remarks Three pumps is enough for one treatment	

Manufacturer/Distributor						
FEI	Name & Address	Home District	Firm Type			
3004432463	G.F. Distributors 34 Linnell Cir Billerica MA 01821-3901	NWE-DO	Distributor			
3010034367	Trademark Cosmetics Inc 545 Columbia Ave Riverside CA 92507-2183	LOS-DO	Manufacturer			

Disposition Date	07/09/2014	
Remarks		
Brazilian Blowout CEO	Mark Brady (877-779-7706 x2150) confirm	ned manufacturer. Mr. Brady advised 2-3 similar complaints received over last 6
years. Complainant giv	es permission to release personal informa	tion to company.
	Problem Keyword	Problem Keyword Details

Initial Disposition

Referred to Other FDA District

Other thinning hair, losing hair

FDA Action Indicated

Initial Evaluation / Initial Disposition

Initial Evaluation

Gender Fel Application Place Sal Application Site Ha Directions Three pumps is enough is enoughirections Followed?			
Gender Fei Application Place Sal Application Site Ha Directions Three pumps is enough is enough Directions Followed? Yes Frequency of Use Other			
Application Place Sal Application Site Ha Directions Three pumps is enough is enough Directions Followed? Yes Frequency of Use Other	(6)	Age	58
Application Site Har Directions Three pumps is enough is enough Directions Followed? Yes Frequency of Use Other	emale	Race	Question Not Asked
Directions Three pumps is enough is enough Directions Followed? Frequency of Use Other	alon/SPA	Reason for Use	Hair Preparations (Non-Coloring)
Three pumps is enough is e	air	Other Products?	Yes
Frequency of Use Oth	ough for o	ne treatment	
	es	Product Duration	
Product Use in Off-Label No	ther	Reaction Site	Scalp
Manner?	0	Off-Label Manner Desc	
Warning Statement on Yes		Warning Statements? This product contains meth well-vetinlated area and on	nylene glyco. When heated, this ingredient releases formaldehyde gas. Use in
Preexisting Conditions? No	0	Treatment	Physician
Current Status Un	nchanged		
Medical Diagnosis		Medical Treatment Dermatologist advised takir	ng 1000mcg Biotin (1 tablet/day)

Remarks

Complainant advises "3 pumps" from product bottle used per hair straightening service. Complainant purchased service 3 times in last 12 months (most recent service done on 04/23/2014).

Adverse Events

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

[Close]

Internet Consumer Report

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

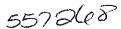
For VOLUNTARY reporting of adverse events, product problems and product use errors

Farm	Approved	OMB No	0910-029	LExpires	12	/31/201
	177		See OMB	statement	on	reverse

Triage unit sequence #

A. PATIENT IN	FORMATION		THE RESERVE	12	Dose or Amount	Freque	ency I	Route	
	2. Age at Time of Event or	3. Sex	4. Weight	#1				-	
b) (6)	Date of Birth:	▼ Female	115 lb						
	(b) (6)	-	10	#2				- 77	
In confidence	(a) (a)	Male	kg						
B. ADVERSE	EVENT, PRODUCT PR	OBLEM OR ER	RROR		tes of Use (If unknown best estimate)	n, give duration	n) from/to		Abated After Use
Check all that apply:					best esumate)		7.7	1	or Dose Reduced
Adverse Even		The state of the s	The second secon	#1				#1 1	es Line Line
Product Use E		ent Manufacturer o	of Same Medicine		agnosis or Reason for	av Han Andianti		#2 🗌 Y	es No Do
Outcomes Attribit (Check all that app	uted to Adverse Event			177.433.3	To straighten an				Reappeared After
Death:	✓ Disa	bility or Permanent	Damage						roduction?
Life-threatening	mm/dd/yyyy)	genital Anomaly/Bir	th Defect	#2				#1 VY	es No Do
		and the second second		6. Lo	t#	7. Expiration	n Date	#2 Y	es No Do
Hospitalization - initial or prolonged ✓ Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices)			#1	.,,	#1		9 NDC	# or Unique ID	
				#2		#2		5, 1455	or dindagin
 Date of Event (m) 07/14/2014 	2227	14/2014	піпиаагуууу)	E	SUSPECT MEDI	CAL DEVIC	F		
E. C.	Problem or Product Use Erro	THE PERSON NAMED IN			and Name	ONE DEVIC			
	ised cosmetologist,		practicing	1					
for approxim	nately 22 years. In	the last five	e years a						
	led Brazilian blowou stments have become			2. Co	mmon Device Name			0	TU
exposure to	the smoke being bur	ned In the a	ir, I						
	nade me sick. I chos er stylist do. Now,			3. Ma	nufacturer Name, Ci	ty and State		UL 1	5 2014
am confident	after last weeks e	xposure that	this					on un 24	W CUIT
	making me very sic			//					
	irn in my throat aft just being at work			4. Model #		Lot#			5. Operator of Dev
	ne. Not it								Health Profess
				Ca	talog #	Expiration	n Date (mm/	(dd/www)	Lay User/Patie
					taiog ii	- Aprilatio	, oute finals		
S Polovant Toetell	aboratory Data, Including Da	thor		-					Other:
D. Relevant Tests/L	aboratory Data, including Da	ites		Se	rial#	Other #			
				6. If I	mplanted, Give Date	(mm/dd/yyyy)	7. If Expl	anted, G	ive Date (mm/dd/yyy
				8. Is t	this a Single-use Dev	vice that was R	Reprocessed	d and Re	used on a Patient?
					Yes No		020,000		
				9. If Y	es to Item No. 8, Ente	r Name and Add	dress of Rep	rocessor	
7. Other Relevant H	istory, Including Preexisting	Medical Condition	ns (e.g.,						
Race: White	egnancy, smoking and alcohol	use, liver/kluney pri	obiems, etc.)	-	THER (CONCO	MITANT NA	EDIONI 6	DODI	OTO
man address.		BT Lales		10000	THER (CONCO	Commission Commission (Commission Commission	ATTENDED TO A CONTRACTOR	A 10 10 10 10 10 10 10 10 10 10 10 10 10	
For addition	nal information see	B/ below.		Frou	act names and there	py dates (excit	ide deadiner	it of even	4
				1			41	-	
				-	REPORTER (See	confidentia	lity sectio	n on ba	ack)
. PRODUCT A	VAILABILITY				me and Address me: (b) (6)				
	or Evaluation? (Do not send)	product to FDA)	-	11	dress:				
Yes No	Returned to Manufacture	er on:							
ш —	DODUCTIES	(mm	(dd/yyyy)	Cit	v:		State	: ZII	9
D. SUSPECT P	RODUCT(S) Manufacturer (trom product la	he0		Phon			E-mail	-	
Mame Kerati		iJel)		(b) (e			(b) (6)		-
Strength:	AND SHOULD BE			-					
Manufacturer					atth Professional?	3. Occupation		A	Also Reported to:
2 Name					Yes No				Manufacturer
Strength;					ou do NOT want your				User Facility
Manufacturer	0 (4(00) Cubotionian		No. of the last	10	the manufacturer, plac	e an A in this	DOX:		Distributor/Impo

B.5. Describe Event or Problem (continued)



... mention my burning eyes, the rash I got across my neck...and many other awful complaints. I am afraid this stuff is going to seriously injure us. It is not right. This has to be stopped. Please advise. Thanks, Stephanie

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

Medical Conditions: Hypothyroid

Allergies: Clindamyacin Important Information:

RX Meds: Levothyroxine 75mcg

OTC Meds: Multivitamin, omega 3,6,9, biotin

MEDWATCH

The FDA Safety Information and

Adverse Event Reporting Program



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

For VOLUNTARY reporting of adverse events, product problems and

product use errors

	See OMB statement on reverse
-	FDA USE ONLY
Triage unit sequence #	561714

A. PATIENT INFORMATION			2. Dose or Amor	unt Frequency	Route
Patient Identifier 2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight	#1		
39 Years		tb	#2		
(b) (6)	☐ Male	or kg	""		
In confidence B. ADVERSE EVENT, PRODUCT PRO Check all that apply:	OBLEM OR E	RROR	3. Dates of Use (#1 (or best estimate) #1 08/20/2014		Stopped or Dose Reduced?
. Adverse Event Product Problem (e.			40	- 102/02/01	#1 Yes No Doesn
Product Use Error Problem with Differe	ent Manufacturer	of Same Medicine		ason for Use (Indication)	#2 Yes No Doesn
2. Outcomes Attributed to Adverse Event (Check all that apply) Death: Disal	bility or Permanent	Damage	#1 Hair straig	the control of the case of the control of the control of the	8. Event Reappeared After Reintroduction?
(mm/dd/yyyy) Life-threatening Cong	th Defect	#2		#1 Yes No Doesr Apply	
☐ Hospitalization - initial or prolonged ☐ Other			6. Lot#	7. Expiration Da	#2 Yes No Doesn
Required Intervention to Prevent Permanent	Impairment/Damag	e (Devices)	#1	#1	9. NDC # or Unique ID
3. Date of Event (mm/dd/yyyy) 4. Dat	te of this Report (mm/dd/yyyy)	#2	#2	
08/20/2014 08/21/2014			The state of the s	MEDICAL DEVICE	
5. Describe Event, Problem or Product Use Erro	OF .		1. Brand Name		
See page 2 for complete text.					
			2. Common Device	Name	CTU
			1		
			2 Manufactures No	ame, City and State	AUG 2 2 2014
			S. Manufacturer Na	ame, City and State	2 2 2017
			4. Model #	Lot#	5. Operator of Device
			5. moutin		Health Professiona
			Catalog #	Expiration D	ate (mm/dd/yyyy) Lay User/Patient
			Catalog #	Expiration	
6. Relevant Tests/Laboratory Data, Including Da	atos			D##	Other:
See page 3 for complete text.			Serial #	Other#	
			6. If Implanted, Giv	re Date (mm/dd/yyyy) 7	. If Explanted, Give Date (mm/dd/yyyy)
				use Device that was Repr	ocessed and Reused on a Patient?
			Yes No	8, Enter Name and Addres	c of Pantagaggar
			9. If Yes to Helli No.	6, Effer Name and Addres	s of Reprocessor
 Other Relevant History, Including Preexisting allergies, race, pregnancy, smoking and alcohol 	Medical Condition use, liver/kidney pro	ns (e.g., roblems, etc.)			
See page 4 for complete text.			F. OTHER (CC	NCOMITANT) MED	ICAL PRODUCTS
				d therapy dates (exclude	
			C DEDORTED	(Can an affiliation lite	anatina an bank
			1. Name and Addre	(See confidentiality	section on back)
C. PRODUCT AVAILABILITY			Name: (b) (6)	1	
Product Available for Evaluation? (Do not send)	product to FDA)		Address		
Yes No Returned to Manufacture	er on:	n/dd/yyyy)			
	Trini.		City		State: ZIP;
D. SUSPECT PRODUCT(S)					
	abel)		Phone #		E-mail
1. Name, Strength, Manufacturer (from product le #1 Name: Brazilian Blowout	abel)		Phone #		(b) (6)
1. Name, Strength, Manufacturer (from product le *1 Name: Brazilian Blowout Strength:	abel)		300	((b) (6)
1. Name, Strength, Manufacturer (from product le #1 Name: Brazilian Blowout Strength: Manufacturer: Brazilian Blowout	abei)		2. Health Profession		(b) (6) 4. Also Reported to:
	ibel)		2. Health Professio	((b) (6)

561714

B.5. Describe Event or Problem (continued)

I got the Brazilian Blowout done 8/21/2014. I voiced my concerns about the products formaldehyde and ask how it bad it was, told her I am very sensitive to chemicals. She said they keep the salon ventilated during the procedure. During the process my stylist had her front door and back door open only and said that would be enough ventilation for the process, but my throat began to get irritated, my eyes and nose burning and i started to cough. She sent me outside for fresh air. The next day I felt worse. Shortness of breath, headache, burning throat, eyes and nose, and feeling sluggish.

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

None

561714

561714

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

Race:--Medical Conditions: None

Allergies: None

Important Information: Sensitive to chemicals

RX Meds: none
OTC Meds: None

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 178816.

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,

Ted Elkin Director

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Internet Consumer Report

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

A PATIENT INFORMATION

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

CIANA	
81990	
	01940

1. Patient Identifier 2. Age at Time of Event or 3. Sex 4. Well (b) (C) Date of Birth:	-		-
(b) (6) Date of Birth: 51 Years (b) (6) Female or	145 lb #2		
In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply: 1. ✓ Adverse Event Product Problem (e.g., defects/malfunctions)	3. Dates of Use (or best estim #1 08/22/201		5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't
Product Use Error Problem with Different Manufacturer of Same	Medicine #2		#2 Tyes TNo TDoesn't
Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent Damage (mm/dd/yyyy)	#1 To calm	Reason for Use (Indication) curly, frizzy hair.	8. Event Reappeared After Reintroduction? #1 Yes No Doesn't
Life-threatening Congenital Anomaly/Birth Defect		10.00000000	Apply #2 Yes No Doesn't
Hospitalization - initial or prolonged Other Serious (Important Medica Required Intervention to Prevent Permanent Impairment/Damage (Device	#41	7. Expiration Da #1	#2 Yes No Doesn't Apply 9. NDC # or Unique ID
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yy	#2	#2	
08/22/2014 08/23/2014		T MEDICAL DEVICE	
5. Describe Event, Problem or Product Use Error See page 2 for complete text.	1. Brand Name		CTU
	2. Common Dev	ice Name	AUG 2 5 201
	3. Manufacturer	Name, City and State	20 2010
	4. Model#	Lot#	5. Operator of Device
			Health Professional
	Catalog #	Expiration Da	ate (mm/dd/yyyy) Lay User/Patient Other:
6. Relevant Tests/Laboratory Data, Including Dates	Serial #	Other#	
	6. If Implanted,	Give Date (mm/dd/yyyy) 7	7. If Explanted, Give Date (mm/dd/yyyy)
	8. Is this a Sing		rocessed and Reused on a Patient?
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	No. 8, Enter Name and Addres	s of Reprocessor
 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, See page 4 for complete text. 	F. OTHER (CONCOMITANT) MED and therapy dates (exclude	ACCUSED AND ADDRESS OF THE PARTY OF THE PART
	G. REPORTE	ER (See confidentiality	section on back)
C. PRODUCT AVAILABILITY Product Available for Evaluation? (Da not send product to FDA) Yes No Returned to Manufacturer on:	Name (b) (6 Address (b)	3) (6)	
D. SUSPECT PRODUCT(S)	City (b) (Slate(b) (6) ZIP (b) (6)
1; Name Strength, Manufacturer (from product label) #1 Name: Brazilian Blowout (Keratin)	Phone # (b) (6)		(b) (6)
Strength: not known by this consumer Manufacturer Brazilian Blowout	2. Health Profes	ssional? 3. Occupation	4 Also Reported to:
#2 Name: Strength: Manufacturer:	5. If you do NOT	want your identity disclosed cturer, place an "X" in this bo	User Facility

B.5. Describe Event or Problem (continued)

561940

I received a Keratin hair treatment-Brazilian Blowout-this afternoon. This was my second treatment at this salon and I hadn't experienced any side effects before. My stylist (both times) assured me that the product he was using is formaldehyde-free. (He used the same product both times) This time after he applied the treatment, my eyes began to water, and soon my nose was running, my throat was tingling and I began coughing. At one point, he gave me a mask (but not at first) and then after I began coughing, he brought out a fan. My symptoms subsideded somewhat, but for a few minutes I was afraid I was going to develop breathing problems and was starting to panic. After my stylist finished drying my hair, I asked him again if there was any formaldehyde or other chemical similar to it in the product and he said no. I told him there was definitely something dangerous in the product and that I wanted to know what it was. He showed me an over the counter product called Brazilian Blowout Acai anti-frizz conditioner (which I purchased) and said it was the same company that made the keratin treatment and that there are no formaledhyde-like chemicals in it. I told him I was going to google it tonight and inform myself b/c there is definitely a dangerous chemical or two in the product he used. I am concerned for myself and for any of the other people in the salon who might have been exposed to the gas from my treatment. I will never submit to a keratin treatment again. I would like to know what the FDA has done and can do to help warn customers and stylists about the hazards of keratin treatments in salons. If these types of treatments are permitted by law (which I don't think they should be), can you require salons to post something about the products, and at least give the customers a verbal warning that they might be endangering their health? Thank you.

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

Race:White
Medical Conditions: none known
Allergies: none known
Important Information: n/a

RX Meds: n/a
OTC Meds: n/a

To Whom It May Concern:

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

Sincerely yours.

Ted Elkin Director

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

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 2

	FDA USE ONLY
Triage unit sequence #	178972

2153

A. PATIENT INFORMATION		D. SUSPEC	T PRODUCT(S)		
Patient Identifier Age at Time of Even Date of Birth:		The second secon	th, Manufacturer (fron	n product label)	
	7 Female 136	#1 224222	an Blow Out		
In confidence (b) (6)	Male	, kg #2			
B. ADVERSE EVENT, PRODUC Check all that apply:	I PROBLEM OR ERROR	2. Dose or Ar	mount	Frequency	Route
	oblem (e.g., defects/malfunctions)	#1		5-	
	th Different Manufacturer of Same Medicine				===
2. Outcomes Attributed to Adverse Event	1-1000-100-100-100-100-100-100-100-100-	#2			
(Check all that apply)			(If unknown, give durat		nt Abated After Use
Death:	Disability or Permanent Damage	best estimate,		100	pped or Dose Reduced? Ves V No Doesn'
(mm/dd/yyyy) Life-threatening	Gongenital Anomaly/Birth Defect	#1 8-30-20	/14		Apply
Hospitalization - initial or prolonged	Other Serious (Important Medical Eve				Yes No Doesn's
Required Intervention to Prevent Perm	nanent Impairment/Damage (Devices)	4. Diagnosis or	Reason for Use (Indica	8. Eve	nt Reappeared After
3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)	#1			ntroduction?
8-30-2014	09/02/2014	#2		#1 L	Yes No Doesn't
5. Describe Event, Problem or Product Us	e Error	6, Lot #	7. Expirati	ion Date #2	Yes No Doesn't
Consumer went to hair Salor		#1	#1	9. NDC	C # or Unique ID
	ree a Brazilian Blow Out. Shair stylist that you cannot	1e #2	#2		
at the last min have a Bran	zillian Blow Out, the reason		T MEDICAL DEV	ICE	
	ed to not put any grease or calp. Consumer agreed and th	e march (March	I MEDICAL DEV	IOL	
hair style done to her head	d. Later that night consumer				
had hair loss and burning sensation, irritation, dry	sensation, itchy, tingling ness. Consumer complains the	2. Common Dev	rice Name		
carbon bioxide, formadahyde	e ingredients are the cause	3. Manufacturer	Name, City and State	-	
her hair and was not given	r approach the person who di a clear answer. Yehia	.a			
Company 1455 East 53rd Chie	cago IL	4. Model #	Lot		5. Operator of Device
					Health Professional
		Catalog #	Exp	piration Date (mm/dd/yyy	y) Lay User/Patient
		Serial #	Oth	er#	Other:
		Serial	Otto	ict a	
		6. If Implanted,	Give Date (mm/dd/yyy)	7. If Explanted, 0	Give Date (mm/dd/yyyy)
		post production of the party of	le-use Device that was No	Reprocessed and Reur	sed on a Patient?
				d Address of Reprocess	104
			13. 4		
6. Relevant Tests/Laboratory Data, Includi	ing Dates				
		_		MEDICAL PRODU	
		Product names	and therapy dates (e)	xclude treatment of event)	
		310			
 Other Relevant History, Including Preex race, pregnancy, smoking and alcohol use 		G. REPORT	ED /Son confide	entiality section on	hack)
race, pregnarcy, arrowing and decertor dec	, irremailey problems, every	1. Name and Ad		entiality section on	Dacky
		(b) (6)			
		Phone # (b) (6)		E-mail	
C. PRODUCT AVAILABILITY		2. Health Profes	sional? 3. Occupation	on	4. Also Reported to:
Product Available for Evaluation? (Do not	send product to FDA)		No		Manufacturer
			I want your identity di	sclosed	User Facility
Yes Z No Returned to	Manufacturer on:(mm/dd/yyyy)		acturer, place an "X" in		☐ Distributor/Importer

Yehia Company 1455 East 53rd Chicago, Illinois 60018

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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,

Ted Elkin Director

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

[Close]

FACTS Interface

FACTS Complaint #137131 (CAER	S #179044)		
Complaint Date	05/27/2014	Complaint Source	Local Government
Accomplishing District	LOS-DO	Complaint Status	Archived
How Received	Telephone		

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

Complaint / Injury

Complaint Description

Complainant is an independent contractor employed by a beauty salon. Reports second hand reactions to the product Brazilian Blowout being used at the salon. Reactions described as nose drainage, racing hearbeat and breathlessness requiring an inhaler. Symptoms began in 2012 and persists. Believes her reaction is related to the abundance of formaldehyde in the product. Product was not used by the complainant but by other employees in the salon.

Adverse Event Result	None
Adverse Event Date	
Notify EIO/EMOPS?	Yes
Notification Date	05/27/2014
Attended Health Professional?	No
Required Hospitalization?	No
Emergency Room/ Outpatient Visit?	No
Reported Complaint To?	
Need Additional/ FDA Contact?	

Remarks

Complaint Symptoms		
Symptom Name	Duration	Remarks
Change in heart rate, pulse; palpitations, fibrillation	null null	racing
Shortness of breath on exertion	null null	
NEC - Identify in Remarks	null null	nose drainage

Health Care Professional

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

Brand Name	Brazilian Blowo	Brazilian Blowout		
Product Name	Acai Profession	al Smoothing Solution		
FDA Product Code	53EY03	Qty/Unit		
UPC Code		Package		
Exp/Use By Date		Lot/Serial	717713H	
Product Used?	No	Purchase Date		
Date Used?		Amount Consumed/Used		
Amount Remained		Date Discontinued		
Country of Origin	Brazil	Imported Product?	No	
Retailer Name	Living Art	Label Remarks		

000001

Manufacturer	Distributor		
FEI	Name & Address	Home District	Firm Type
3008593985	Brazilian Blowout 6855 Tujunga Ave North Hollywood CA 91605-6312	LOS-DO	Distributor
3007129680	Cadiveu Cosmeticos Martim De Sa 75 Sao Paulo null null		Manufacturer

Initial Evaluation / Init	ial Disposition			
Initial Evaluation	FDA Action Indicated	Initial Disposition	Referred to Other FDA District	
Disposition Date	06/03/2014			
Remarks				
No additional product in	formation provided.			
	Problem Keyword		Problem Keyword Details	
Reaction		drainage, racing heatbeat.	breathlessness	

Cosmetic			
Cosmetic ID #(b) (6)			
DOB		Age	
Gender	Female	Race	
Application Place	Other	Reason for Use	Hair Preparations (Non-Coloring)
Application Site	Hair	Other Products?	
Directions			
Directions Followed?		Product Duration	
Frequency of Use		Reaction Site	Other
Product Use in Off-Label Manner?		Off-Label Manner Desc	
Warning Statement on Label?		Warning Statements?	
Preexisting Conditions?		Treatment	
Current Status			
Medical Diagnosis		Medical Treatment	
Remarks second hand exposure			

Adverse Events

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

[Close]

Cadiveu Cosmeticos Martim De Sa 75 Sao Paulo, Brazil

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 # 179044.

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,

Ted Elkii Director

Office of Analytics and Outreach

Center for Food Safety and Applied Nutrition

Internet Consumer Report

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

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

	FDA USE ONLY	
nage unit equence #	564025	

MEDWATCH
The FDA Safety Information and
Adverse Event Reporting Program

A. PATIENT IN	NFORMATION				Dose or Amount		requency	Route	
	2. Age at Time of Event or Date of Birth:	3. Sex	4 Weight	#1	1.1.1	11	**	**	
(b) (6)	29 Years	✓ Female	137 10	#2					
	(b) (6)	Male	or kg	11/2					
In confidence	EVENT, PRODUCT PRO	ORI EM OR E		3 Da	tes of Use (If unkn	nown ann d	unitari termite	5 Evan	t Abated After Use
Check all that apply:	EVENT, PRODUCT PRO	JBLEM OR E	KKOK	(or	best estimate)	idivii, give di	uraciony nomina		d or Dose Reduced?
Adverse Even	nt Product Problem (e.g	g., defects/malfund	ctions)	#1				#1 🔲 ነ	Yes No Does
Product Use E	Error Problem with Differe	nt Manufacturer	of Same Medicine	#2				#2 🗔	7 75
	outed to Adverse Event			100	agnosis or Reason	n for Use (Ir	ndication)		- Apply
(Check all that ap		10/ D	5	#1					t Reappeared After troduction?
Death:	(mm/dd/yyyy)	pility or Permanent		#2				#1 DY	Yes No Does
Life-threatenin		enital Anomaly/Bi			-	12.5		#2 🗍 \	Yes No Does
	- initial or prolonged Other			6. Lot	Ł#	7. Exp	iration Date		Apply
	vention to Prevent Permanent I	mpairment/Damag	ge (Devices)	#2		#2		_ 9. NDC	# or Unique ID
3. Date of Event (m		e of this Report (mm/dd/yyyy)	1	CHERECT ME		EVICE	-	_
08/15/2014		10/2014			SUSPECT ME and Name	DICAL D	EVICE		
	Problem or Product Use Erro for complete text.	r		1. Die	and Name				
Los page E	semparas vana								
				2. Co	mmon Device Na	me		Port	U
								. 41	
				3. Ma	nufacturer Name,	, City and S	tate S	EPIT	2014
									-41
				4. Mo	idel#	Lot	#		5. Operator of Devic
									Health Profession
				Cal	talog #	Exp	iration Date (n	nm/dd/vvvv)	Lav User/Patient
					3/12	_ 175			
6 Relevant Tests/L	aboratory Data, Including Da	tes		-	-121.0	Otto	er#		Other:
	for complete text.			36	rial#	Oth	er #		
								3	
				6. If I	mplanted, Give Da	ate (mm/dd/)	yyyy) 7. If E	cplanted, G	Give Date (mm/dd/yyyy,
				8. ls t	his a Single-use	Device that	was Reproces	sed and Re	eused on a Patient?
				1000	Yes No				
				9. If Y	es to Item No. 8, E	nter Name a	nd Address of F	eprocessor	
7. Other Relevant H	listory, Including Preexisting	Medical Conditio	ns (e.g.,	1					
allergies, race, pri	egnancy, smoking and alcohol of for complete text.	use, liver/kidney p	roblems, etc.)				-		25.4E
see page 4	TOT COMPTETE CEXT.			_	THER (CONC		The state of the s		
				Produ	uct names and the	erapy dates	(exclude treatn	nent of even	11)
				G. R	REPORTER (S	ee confid	entiality sec	tion on b	ack)
C DROBUGE	AVAII ADII ITV			1. Na	me and Address				
C. PRODUCT A	AVAILABILITY for Evaluation? (Do not send p	product to EDAL		1	me: Florence	Millon			
				Add	dress:				
Yes No	Returned to Manufacture	mn (mn	vlad/yyyy)		lur -				
D. SUSPECT P				Phon				ale: ZI	F
1. Name, Strength, Manufacturer (from product label) #1. Name: Brazilian Blowout				Phon (b)			(b)		100
	ilian Blowout			(0)	(0)		(10)	(0)	
Manufacturer				2000	alth Professional	? 3. Occup	ation	4	Also Reported to:
2 Name:				L	Yes No				Manufacturer
Strength:					ou do NOT want yo			7	User Facility
Manufacturer:					the manufacturer, p	place an "X"	in this box:		Distributor/Importe

564025

B.5. Describe Event or Problem (continued)

On August 15, 2014 I had a Brazilian Blowout. On August 29, 2014 I erupted into a debilitating rash from head to toe. Multiple doctors visits and biopsies. Rash continues to worsen and today is September 10, 2014.

Biopsy of neck lesion: eczematous dermatitis

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

Race:White Medical Conditions: Allergies: NKDA Important Information: RX Meds: After incident, Erythromycin, Triamcinolone, Clobetsol OTC Meds: Hydrocortisone, Benadryl

Triage unit sequence #

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Form Approved: OMB No				
	266	OWB	statement	on reverse
	-			

A PATIENT	INFORMATION	3	-		2. Dos	e or Amount	Freque	nev	Route		
STATE OF THE PARTY	er 2. Age at Time of	Event or	3, Sex	4. Weight	#1		-				
(b) (6)	(b) (6)	000	Female	lb							
200,000	(0) (0)	-	☐ Male	or kg	#2						
In confidence	E EVENT, PROD	UCT PRO	DBLEM OR E		3. Dates	of Use (If unknow	n give duration	i) from/to	5. Event	Abated Aft	er Usa
Check all that app	COLOR STREET,	001111	JOEEM SILE	inon.	(or bes	st estimate)	n. give dansilei	y months	Stopped	or Dose Re	duced?
1. Adverse Ev			g., defects/malfun		#1				#1 LY	es V No	☐ Doe:
Product Us			nt Manufacturer	of Same Medicine	#2	osis or Reason fo	r Hea (Indicati	201	#2 🗆 Y	es No	Doe
2. Outcomes Att (Check all that	ributed to Adverse E appiy)	vent			1000	aightening th	The second second	31.7		Reappeare	
Death:	famous falail 6 a a a a	✓ Disal	oility or Permanen	t Damage	#2			_		reduction?	Doe:
Life-threate	(mm/dd/yyyy) ning	☐ Cong	enital Anomaly/Bi	rth Defect							Appl
☐ Hospitalizat	ion - initial or prolonge	d Other	Serious (Importa	nt Medical Events)	6. Lot#		7. Expiration	Date	#2 L Y	es No	☐ Doe App
Required In	tervention to Prevent i	Permanent I	mpairment/Dama	ge (Devices)	#1		-		9. NDC #	or Unique	ID
3. Date of Event			e of this Report (mm/dd/yyyy)		CDEOT MEDI	#2	-		_	
01/07/201	nt, Problem or Produc		08/2015		1. Brand	SPECT MEDI	CAL DEVIC	E			
	for complete					1.00.00					
					2 Comm	on Device Name		- 67	U		
					2. Comm	on Device Name					
				-				IAN -	2015		
					3. Manuf	acturer Name, Ci	ty and State				
							Dec.				
					4. Model	#	Lot#	-	-	5. Operator	of Devi
										Health F	Professio
					Catalo	a#	Expiratio	n Date (mn	v/dd/vvvv)	Lay Use	er/Patient
						3."					
6. Relevant Test	s/Laboratory Data, In	cluding Da	tes		Serial	4	Other#	_	_	Other:	
					Serial		Outer in				
				1.0	6 If land	anted, Give Date	/mm/ddhnani	7 16 Eve	lantad C	ive Date (mi	m/ddhnan
				- 7	o. n unpi	anteu, Give Date	(IIIII GG/yyyy)	7. II LAP	iaineu, o	We Date (IIII	n/uu/yyy)
				-		a Single-use Dev	rice that was F	eprocesse	d and Re	used on a P	atient?
						o Item No. 8, Ente	r Name and Add	ress of Re	processor		
7 DIL - D L	eura e tectulose	Second attack	Manufact Manadata		Service Co	ALL CONTRACTOR OF THE PARTY OF			1		
allergies, race.	t History, Including F pregnancy, smoking a	and alcohol i									
See page	f for complete	text.			THE R. P. LEWIS CO., LANSING, MICH.	IER (CONCO					
					Product	names and there	py dates (exclu	ide treatme	nt of even	0	
						ORTER (See	confidentia	lity secti	on on ba	ack)	
C. PRODUC	TAVAILABILITY	5500	F-100 L		1. Name	and Address					
	le for Evaluation? (De		roduct to FDA)		25/7 - 25/10	s (b) (6)					
Yes VN	Returned to I	Manufacture	r on:	n telefit a anal							
D. SUSPECT	PRODUCT(S)		(mn	n/dd/yyyy)	City: (t	0) (6)		Stat	e: Inite Zir	P: (b) (6)	
1. Name, Strengt	th, Manufacturer (from				Phone #			E-mail			
#1 Name: Kera Strength: ?w:	tin treatment	Rejuveno	1		(b) (6)			(b) (6)			
	Rejuvenol				2. Health	Professional?	3. Occupation		4.	Also Repo	rted to:
#2 Name:					□ Ye	s 🗌 No				Manufa	
Strength:						do NOT want your manufacturer, plac				User Fa	icility tor/Import
Manufacturer:					to the	manufacturer, plac	e an A in this	DOX:		Distribu	

578527

B.5. Describe Event or Problem (continued)

I can't stop coughing and its hard to breathe after this keratin treatment (rejuvenol) at the salon synergy on 981 N Wales road, PA 19454

Rejuvenol 415 Bayview Ave Amityville, New York 11701

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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



MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Form Appro	See OMB statement on reverse.
7	FDA USE ONLY
Triage unit	1199E0

A. PATIENT INFORMATION	2. Dose or Amount	Frequency	Route
1. Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight (b) (c) Date of Birth:	#1		-
(b) (c) Female 148			
☐ Male or	#2 kg		
In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR		nown, give duration) from/to	5. Event Abated After Use
theck all that apply:	(or best estimate)	nown, give duration) frontist	Stopped or Dose Reduced?
Adverse Event Product Problem (e.g., delects/malfunctions)	#1 01/08/2015 -		#1 Yes No Doesr
Product Use Error Problem with Different Manufacturer of Same Medic	ine #2		#2 Yes No Doesn
Outcomes Attributed to Adverse Event	4. Diagnosis or Reaso	A STATE OF THE STA	Apply
(Check all that apply) ☐ Death: ✓ Disability or Permanent Damage	#1 This product of professional s	was applied by a stylist at salon	8. Event Reappeared After Reintroduction?
(mm/dd/yyyy)	#2		#1 Yes No Doesn
Life-threatening Congenital Anomaly/Birth Defect		7-2-3	#2 Yes No Doesn
Hospitalization - initial or prolonged Other Serious (Important Medical Even	ts) 6. Lot #	7. Expiration Date #1	Apply
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	#2		9. NDC # or Unique ID
Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)	200	#2	
01/08/2015 01/14/2015	E. SUSPECT ME	DICAL DEVICE	
Describe Event, Problem or Product Use Error See page 2 for complete text.	1. Diana Maine		
MATERIAL STATE AND STATE AND STATES			
	2. Common Device Na	me	protection of
	10000		CTU
	3. Manufacturer Name	City and State	THE STATE OF
	A special		JAN 1 5 2015
	4. Model #	Lot#	5. Operator of Device
			Health Profession
	Catalog #	Expiration Date (n	mm/dd/yyyy) Lay User/Patient
		200000000	Other
Relevant Tests/Laboratory Data, Including Dates	Serial #	Other#	Other.
See page 3 for complete text.	Sullar W	Other #	
	6 11 1 1 1 1 1 1		
	6. If Implanted, Give D	ate (mm/dd/yyyy) 7. If E	xplanted, Give Date (mm/dd/yyyy)
	8. Is this a Single-use	Device that was Reproces	ssed and Reused on a Patient?
	Yes No	COLL STREET	Charles W. Jan.
	9. If Yes to Item No. 8, E	nter Name and Address of F	Reprocessor
Other Relevant History, Including Preexisting Medical Conditions (e.g.,			
allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) See page 4 for complete text.	E OFFICE	NOWE WE WERE	PROPUSTS
The same of the sa	The second secon	OMITANT) MEDICA erapy dates (exclude freatr	N - 1 - 2 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1
	Froduct names and th	erapy dates (exclude treatr	nem or event)
		ee confidentiality sec	tion on back)
. PRODUCT AVAILABILITY	1. Name and Address		
roduct Available for Evaluation? (Do not send product to FDA)	Name: (b) (6) Address: (b) (6)		
Yes No Returned to Manufacturer on:	(D) (O)		
(mm/ad/yyyy)	City (by (c)		tate (6) (6)
. SUSPECT PRODUCT(S)	City: (b) (6)	E-mai	77100000
Name, Strength, Manufacturer (from product label) Name: Brazillan Blowout	(b) (6)	(b) (6)	
Strength:			
Manufacturer	2. Health Professional	7 3. Occupation	4. Also Reported to:
Name:	Yes No		✓ Manufacturer
Strength:	5. If you do NOT want yo		User Facility
Manufacturer:	to the manufacturer,	place an "X" in this box:	☐ Distributor/Importe

B.5. Describe Event or Problem (continued)

I had an appointment on 1/8/2015 to have a Brazilian Blowout at a salon. The process took approximately 2.5 hours and it looked great. By later in the afternoon I was experience a tingling sensation on my scalp, neck and face. by 9:30pm I felt like my scalp, neck and face were burning. I contacted the stylist who did not answer. I called her partner and she told me to wash my hair. I washed several times and the pain subsided only minimally but it didn't go away. Later that night, I had a burning feeling in my throat and nose which went away by the end of the next day. Over the next few days I had on and off pain anywhere my long hair touched on my body, neck back, ears,.... I washed with eggs, salt and coconut oil as recommended by others online. Still nothing worked. By Tuesday I was in worse pain and today, Wednesday, I am experiencing a horrible amount of burning and pain. I can't bear to have my hair touch any part of me. I am considering cutting all of my hair off because I can't stand this... and I have always loved having my long hair. I am afraid of what I have read online and to see that this product and others like it are still on the market. I fear it will continue to get worse. I urge anyone in a position to ban this product to please do so. I can be reached at 727-729-2699. Sincerely, Jennifer Thayer

No tests taken at this point

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

Race:White Medical Conditions: None

Allergies: Penicillin, Morphine, Neosporin

Important Information: I have never been pregnant nor do I smoke. I drink only socially (2-4 drinks per week max)

OTC Meds: Vitamin C, Magnesium Glycinate, AdvaClear, UltraInflamX plus 360 - all of these items are mainly used to help with this issue.

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

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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

MEDWATCH

The FDA Safety Information and

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

FDA USE ONLY
Triage unit sequence # 583817

Adverse Event Reporting Program A. PATIENT INFORMATION Dose or Amount Frequency Route 1 Patient Identifier | 2. Age at Time of Event or . Weight Date of Birth: (b) (6) 162 tb ✓ Female (b) (6) #2 __ Male ka In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Dates of Use (If unknown, give duration) from/to (or best estimate) 5. Event Abated After Use Stopped or Dose Reduced? Check all that apply Doesn't #1 Yes No 1. Adverse Event Product Problem (e.g., defects/malfunctions) #2 Product Use Error Problem with Different Manufacturer of Same Medicine Doesn't #2 Yes No Apply 4. Diagnosis or Reason for Use (Indication) Outcomes Attributed to Adverse Event (Check all that apply) 8. Event Reappeared After #1 straighten hair Reintroduction? Death: Disability or Permanent Damage #1 Yes No Doesn't #2 (mm/dd/yyyy) Apply Life-threatening Congenital Anomaly/Birth Defect #2 Yes No Daesn't Apply 6. Lot # 7. Expiration Date ☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events) #1 #1 Required Intervention to Prevent Permanent Impairment/Damage (Devices) 9. NDC # or Unique ID #2 #2 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) E. SUSPECT MEDICAL DEVICE 02/11/2015 02/13/2015 1. Brand Name 5. Describe Event, Problem or Product Use Error See page 2 for complete text. 2. Common Device Name OR USE BLACK INK 3. Manufacturer Name, City and State 4. Model # Lot# 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Other 6. Relevant Tests/Laboratory Data, Including Dates Serial # Other# EASE F 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor Other Rejevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) See page 4 for complete text. F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) G. REPORTER (See confidentiality section on back) 1. Name and Address C. PRODUCT AVAILABILITY Name: (b) (6) Product Available for Evaluation? (Do not send product to FDA) Address (b) (6) Yes No Returned to Manufacturer on: (mm/dd/yyyy) State (6) (6) (6) City (b) (6) D. SUSPECT PRODUCT(S) Phone # E-mail 1. Name, Strength, Manufacturer (from product label) (b) (6) (b) (6) #1 Name Original Resatin Strength: 2. Health Professional? 3. Occupation 4. Also Reported to: Manufacturer Manufacturer Yes No #2 Name: User Facility Strength: 5. If you do NOT want your identity disclosed Distributor/Importer Manufacturer. to the manufacturer, place an "X" in this box:

B.5. Describe Event or Problem (continued)

583819

I received a brazilian hair straightening treatment on 2/11/15 in which Original Keratin product was used. My eyes and nose burned significantly while it was being applied. My scalp burned a little. That evening when I went to bed my eyes and nose started burning again keeping me awake. The skin around the hairline of my face was red. I washed my hair several times. It is now 2/13/15 and my skin is still somewhat red. I still get a headache everyday. It feels like a sinus headache. My eyes are burning but not sure if it's from the hair straightening.

30005

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

Race:White Medical Conditions: low thyroid

583819

Allergies: none

Important Information: none

RX Meds: 75 mg levothyroxine daily

OTC Meds: green vibrance, vitamin d, calcium, fish oil

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

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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

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Internet Consumer	Report	FS/	1/19	nn Approved: OMB No.	.0910-0291, Expires: 12/31/2011 See OMB statement on reverse.
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For VOLUNTARY reporting of adverse events, product problems and product use errors

	FDA USE ONLY	
Triage unit sequence #		
	590205	-1

A. PATIENT IN	FORMATION	William III		2. Dose or Amo	ount Freq	uency	Routa	
Albert Control	2. Age at Time of Event of Date of Birth:	3. Sex	4. Weight	#1				
b) (6)	36 Years	✓ Female	215 lb	#0				
CHI.	(b) (6)	☐ Maie	or kg	#2				
AND DESCRIPTION OF THE PERSON	EVENT, PRODUCT P	ROBLEM OR E		3. Dates of Use (I. (or best estimat	f unknown, give durati le)	ion) from/to		Abated After Use or Dose Reduced?
heck all that apply: Adverse Event			The second secon		- 03/29/2015	4	12.00	es No Does Apply
land .	rror Problem with Diffe	erent Manufacturer	of Same Medicine		leason for Use (Indica	alian)	#2 Y	es No Does
(Check all that app		sability or Permanent	Damage	#1 Dying my h	A STATE OF STREET AND A STREET ASSESSMENT	story	Reintr	Reappeared After oduction?
Life-threatening	nm/dd/yyyy)	ongenital Anomaly/Bit	th Defect	#2			#1Y	es No Does Apply
	- Initial or prolonged 🕜 Oti	S. S. Land and S. Land and S. L. Sand		6. Lot#	7. Expirati	ion Date	#2 Y	os No Does
Required Interv	ention to Prevent Permaner	nt Impairment/Damag	ge (Devices)	#1	#1		9. NDC #	or Unique ID
B. Date of Event (mr	n/dd/yyyy) 4. E	ate of this Report (mm/dd/yyyy)	#2	#2			
03/29/2015	03	3/31/2015		Secretary of the second of the	MEDICAL DEVI	ICE		
. Describe Event, F	Problem or Product Use E	rror		1. Brand Name				
				2. Common Device	ce Name	-	_	cru
								No III
See additi	onal page(s)	for comple	ete text.	3. Manufacturer N	Name, City and State			APR - 1 2015
				4. Model #	Lot#			5. Operator of Device
							477	Health Profession
				Catalog #	Expirat	ion Date (mn	vaaryyyy)	Lay User/Patient Other:
. Relevant Tests/La	aboratory Data, Including	Dates		Serial#	Other #			
				6. If implanted, G	ive Date (mm/dd/yyyy	7. If Exp	lanted, Gi	ve Date (mm/dd/yyyy)
				8. Is this a Single	-use Device that was	Reprocesse	d and Reu	sed on a Patient?
					o. 8, Enter Name and A	ddress of Rep	processor	
	story, including Preexisting gnancy, smoking and alcoh							
					ONCOMITANT) I			
See additi	onal page(s)	for comple	ete text.		ional page			
					R (See confident	iality section	on on ba	ck)
. PRODUCT A				1. Name and Add Name; (b) (6)				
Yes No	Returned to Manufacti			Address (b) (6)				
		(min	VBd/yyyy)	City: Tampa		State	e: FL ZIP	33629
SUSPECT P		Inhall	- 06.0	Phone #		E-mail		22062
Name, Strength, I Name: Keratii	Manufacturer (from product	(abel)		(b) (6)		(b) (6)		
Strength: Cashn	ere brown			- W. W W W.			- 17	Alon Done de da
Manufacturer. sc	chwarzkopf				Ional? 3. Occupatio	n	1000	Also Reported to: Manufacturer
Name: Strength:				Yes No	vant your identity disci	hasad		User Facility
Strength: Manufacturer:					urer, place an "X" in the			Distributor/Importe

B.5. Describe Event or Problem (continued)

I used Schwarzkopf Keratin Color Cashmere brown. I have dyed my hair many times but this is the first time with this product. I followed all directions with exception of doing an allergy test. When I was washing out the product I noticed hives on my torso, upper legs, chest, neck and back. I rinsed out my hair and took Benadryl. The next day I saw my doctor and got a steroid shot. Although my hives have mostly faded, I am still-very itchy two days later.

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

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

Race: White

Medical Conditions: None

Allergies: pollen, dust

Important Information: None

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

RX Meds:

OTC Meds: allegra, citracal, vitamin D

Schwarzkopf

,

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 # 184344.

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

Internet Consumer Report

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

Expires: 12/31/2011 atement on reverse,

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

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

2. Dose or Amount

	See OMB statement on reverse
	FDA USE ONLY
Triage unit sequence #	manufacture .
5	94/69
Frequency	Route
	-

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight	#1				
	59 Years	Female		#2				
In confidence	A THOUGHT AND ADDRESS OF THE PARTY.	☐ Male	kg					
B. ADVERSE Check all that apply: 1. Adverse Ever				(or best est #1 04/21/2		ve duration)	Stoppe	t Abated After Use d or Dose Reduced? Yes No Doesn' Apply
	Error Problem with Differen	ent Manufacturer	of Same Medicine	#2	- Discount of the	- Nadelle	#2 🗆	
(Check all that ap	-	bility or Permanent	Damage		or Reason for Us		hair 8. Even	t Reappeared After troduction? Yes No Doesn Apply
Life-threatenin		genital Anomaly/Bir r Serious (Importar		6. Lot#	7.	Expiration	Date #2	
The state of the s	vention to Prevent Permanent			#1	#1		9. NDC	# or Unique ID
3. Date of Event (m	State of the state	te of this Report (mm/dd/yyyy)	#2	#2			
04/21/2015 5. Describe Event,	Problem or Product Use Erro	/24/2015 or		1. Brand Nam	ECT MEDICAL	DEVICE		17000
11 - 7				2. Common D	levice Name			CIU
								APR 27 2015
See addit:	ional page(s) f	or comple	ete text.	3. Manufactur	rer Name, City an	d State		AFR 202 ZUIS
				4. Model#		Lot#		5. Operator of Device Health Professional
				Catalog #		Expiration	Date (mm/dd/yyyy)	
6. Relevant Tests/L	aboratory Data, Including Da	ites		Serial#		Other#		Other:
				6. If Implanted	d, Give Date (mm	(dd/yyyy)	7. If Explanted, G	Give Date (mm/dd/yyyy)
				8. Is this a Sir		hat was Re	processed and Re	eused on a Patient?
				9. If Yes to Iter	n No. 8, Enter Nan	ne and Addr	ess of Reprocesso	
7. Other Relevant H allergies, race, pri	listory, including Preexisting egnancy, smoking and alcohol	Medical Conditio use, liver/kidney pr	ns (e.g., oblems, etc.)	E OTHER	CONCOMIT	ANT\ ME	DICAL PRODI	ICTS
See additi	ional page(s) f	or comple	te text.				e treatment of ever	124
				G. REPOR		fidentiali	ty section on b	ack)
C. PRODUCT				Name: (b) (24-14-4			
	or Evaluation? (Do not send p	er on:		Address:	7			
D. SUSPECT P			/ad/yyyy)	City:			State: Zi	P
	Manufacturer (from product la	bel)		Phone #	(E-mail (b) (6)	_
Manufacturer:					fessional? 3. Occ	cupation	4	. Also Reported to:
#2 Name: Strength:				5. If you do NO		ity disclose	d	Manufacturer User Facility
Manufacturer:				5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:				

594169

B.5. Describe Event or Problem (continued)

I developed eye problem after my hair stylist used a new product (Brazilian Blowout) on my hair. I didn't know she was putting it on my hair until after she had put it in my hair. When I commented on the smell, she told me it was Brazilian Blowout. The Salon is Kim's Total Salon Spa at 8785 Center Parkway, Ste 330B, Sacramento CA 95823. The date of my hair appointment was 4-21-15. I noticed blurry vision that night. The next day I started having light flashes. I called my eye clinic on 4-23-15 and was told I should come in that day for an eye exam. My eye doctor diagnosed posterior vitreous detachment. I am under watch for progression to a possible retinal detachment. I am not sure if the product treatment caused or contributed to this eye problem or if it is coincidental.

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

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

Race: White

Medical Conditions:

Allergies:

Important Information:

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

Internet Consumer Report

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

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S	A Second Charles on the Charles Control of the Control of the Charles of the Char
cort	Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.
ing of	FDA USE ONLY
lems and	Triage unil sequence #
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		2. Dose or Amou	int Frequency	Route		
Event or 3. Sex	4. Weight	#1		1		
[7] Female	lb	#2				
☐ Male	or 78 kg					
B, ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply:				Stopped o	5. Event Abated After Use Stopped or Dose Reduced? #1 Yes \(\) No \(\) Doesn	
. ✓ Adverse Event ✓ Product Problem (e.g., defects/malfunctions) Product Use Error ✓ Problem with Different Manufacturer of Same Medicine				#2 \\\\	#2 Tyes No Docsn't	
2. Outcomes Attributed to Adverse Event (Check all that apply)				8. Event R	8. Evont Reappeared After Reintroduction?	
Death: ✓ Disability or Permanent Damage (mm/dd/yyyy) Life-threatening				#1 Yes	#1 Yes No Doesn'	
				e #2 Yes		
ermanent Impairment/Damag	ge (Devices)	9.4		9. NDC # o	r Unique ID	
	mm/dd/yyyy)	27	The state of the s			
06/23/2015		THE RESIDENCE AND PROPERTY OF THE PROPERTY OF	MEDICAL DEVICE	-		
Use Error		n Dianu Name			CTU	
		2. Common Device	Name		JUN 2 4 2019	
(s) for comple	ete text.	3. Manufacturer Na	me, City and State		SON WEEDIN	
		4 Model#	Lot#	5.	Operator of Device	
	_]	a. Model w			Health Professional	
			Expiration Dat	Expiration Date (mm/dd/yyyy) Lay U		
6. Relevant Tests/Laboratory Data, Including Dates			Other#			
	- 4	6. If Implanted, Giv	e Date (mm/dd/yyyy) 7.	If Explanted, Give	Date (mm/dd/yyyy)	
	39	8. Is this a Single-u	se Device that was Repro	cessed and Reus	ed on a Patient?	
reavisting Medical Condition	ne (a n	9. If Yes to Item No.	8, Enter Name and Address	of Reprocessor		
d alcohol use, liver/kidney pr	roblems, etc.)				TS	
(s) for comple	ete text.				lete text.	
		LC DEPORTER	(See confidentiality :	section on bac	A	
		Section of the Control of the Contro	The Line Law and the Control of the		K)	
not send product to FDA)		1. Name and Addre Name (b) (6) Address (b) (6)	The Line Law and the Control of the		K)	
anufacturer on	n/dd/yyyy)	1. Name and Addre Name (b) (6) Address (b) (6)	The Line Law and the Control of the	State (b) (617) P (
anufacturer on(mm	v/dd/yyyy)	1, Name and Addre Name: (b) (6)	ss	State (b) (6) ZIP (
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i e	Female Male Male Male Male CT PROBLEM OR E Oblem (e.g., defects/malfunce of the Different Manufacturer of the Different Manufacturer of the Different Manufacturer of the Different Manufacturer of the Disability or Permanent Congenital Anomaly/Bit Other Serious (Importangemanent Impairment/Damagemanent Impairment/Damagemanent/Dama	Female		CT PROBLEM OR ERROR 10 10 10 10 10 10 10 1	CT PROBLEM OR ERROR 10 22 3. Dates of Use (if unknown, give duration) fromth (or best estimate) 42 4. Disploitly or Permanent Damage 2. Date of this Report (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 5. Date of this Report (mm/dd/yyyy) 6. Lot # 4. Model # Lot # 2. Common Device Name 2. Common Device Name 3. Manufacturer Name, City and State 4. Model # Lot # Expiration Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give 3. Is this a Single-use Device that was Reprocessed and Reus Yes No 9. If Yes to Item No. 3, Enter Name and Address of Reprocessor 4 date of Juse, Iliverhidney problems, etc.) F. OTHER (CONCOMITANT) MEDICAL PRODUC Product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of event) 4 date of the product names and therapy dates (exclude treatment of eve	

B.5. Describe Event or Problem (continued)

I used keratin hair treatment many times in the past without any reaction/problem. After moving to California I chose a new hair salon (My Blow LA, in Irvine Spectrum center). Despite claim by beauty salon for using formaldehyde free products I had abnormal eye and breath burning during application which was reassured by the stylist that "it is normal smell". Scalp itching started about 4 hours after the application. Severe scalp edema started about 12 hrs after application and despite washing my head several times it got worse and in 24 hours and I had severe periorbital edema and facial edema. At this point I could barely open my eyes. It was necessary to receive several corticosteroid injections to treat this reaction and it resolved very slowly within the next 6 days.

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

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

Race: White

Medical Conditions: Hypothyroidism

Allergies: Latex

Important Information: Not using alcohol, tobacco or any other drugs

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

RX Meds: Levothyroxine, 75 mcg daily

OTC Meds: Multivitamins one daily Calcium tablet one daily

GK Hair 4800 NW 15th Ave., Suite E Fort Lauderdale, Florida 33309

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 # 187325.

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

Internet Consume Report

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

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

	FDA USE ONLY
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	1017597

A. PATIENT	NFORMATION		100000000000000000000000000000000000000	2.	Dose or Amount	-	Freque	Le D 7		
	2 Age at Time of Event or Date of Birth: 40 Years	Female	4. Weight 135 to	#1	spply light	ly to	morths	F SEE PARK	d to a surface. Y the skin	
In confidence		☐ Male	or kg							
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply; 1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine			3. Dates of Use (If unknown, give duration) from/to (or best estimate) #1 07/08/2015 - #2				Stopp	5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn		
							un T	Yes No Does		
2. Outcomes Attributed to Adverse Event (Chock all that apply) Death (Intrividal/yyyy) Life-threatening Congenital Anomaly/Birth Defect Hospitalization - Initial or prolonged. Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices)			4. Diagnosis or Reason for Use (Indication) #1 hair straightening and reduce frizz product #2				ee 8. Eve Rei	8. Event Reappeared After Reintroduction?		
			6. Lot# 7. Expiration Date			Date #2	#2 Yes No Doesn Apply 9. NDC # or Unique ID			
			#1 120015F2 #1		1,370,371,371,371					
	Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)		W. 20-10010	#2 #2						
07/08/2015	[1]				E. SUSPECT MEDICAL DEVICE					
. Describe Event,	, Problem or Product Use En	ror	71	1. Br	and Name					
			1	2, Co	ommon Device Na	ame			CI	
See addit	ional page(s)	for comple	ete text.	3. Ma	anufacturer Name	e, City an	d State		JUL 2	
				4. Model # Lot #				5. Operator of Device Health Professional m/dd/yyyy) Lay User/Patient		
			1	Catalog # Expiration Date (m		Date (mm/dd/yyy				
						-			Other:	
Relevant Tests/Laboratory Data, Including Dates			Se	rial#	1	Other#				
See addit	ional page(s)	for comple	ete text.	6. If I	mplanted, Give D	Date (mm)	(dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yyyy)	
				1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	this a Single-use	Device t	hat was R	eprocessed and f	Reused on a Patient?	
Other Palevant	History, Including Preexistin	a Madiani Canditia	no 10 m	9, 11)	es to Item No. 8, I	Enter Nam	e and Add	ress of Reprocess	or	
allergies, race, p.	regnancy, smoking and alcoho	l use, liver/kidney p	roblems, etc.)					EDICAL PROD		
See addit	ional page(s)	for comple	ete text.					de treatment of evens	mplete text	
DDANIE -	ALIAN ARIDATA	- 35		The same of	REPORTER (S		fidential	ity section on	back)	
	AVAILABILITY for Evaluation? Do not send	t product to FDA)		527°Ta	ame (b) (6) idress (b) (6)	28				
Yes No	Returned to Manufacture	rer on:(mn	Vad/yyyy)					San de seus		
. SUSPECT	PRODUCT(S)			-	y: Fargo		State, ND ZIP: 58102			
	, Manufacturer (from product	label)		Phor (b) (6				E-mail (b) (6)		

FORM FDA 3500 (1/09)

#2 Name:

Strength

Manufacturer

Manufacturer Mallibu California 877-779-7706

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

Yes No

2. Health Professional? 3. Occupation

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

Distributor/Importer

4 Also Reported to:

V Manufacturer

User Facility

B.5 Describe Event or Problem (continued)

experienced severe tachycardia after Brazilian Blowout was applied to hair and scalp. I had this treatment applied at the Primp Salon at Crabtree Valley MalI in Raleigh NC while visiting family and friends on vacation. Their telephone number is 984-232-8652. I became very scared and told the stylist that if my heart rate did not slow down then we may have to call the paramedics. The Stylist told me I was probably having a reaction to the formaldehyde. I became very dizzy and tingling sensation from head to toe. I thought I was going to faint so I requested water. In a few minutes I did start to feel a little better and the tachycardia was starting to blow down. I didn't feel like myself for 24 hours.... The sensation of being light-headed and feeling faint would come and go, I definitely was experiencing a systemic reaction to the product. My hands are still peeling from the formaldehyde that was in the product. I also experienced dry mouth and bands of perspiration across different parts of my body during the First 24-48 hours. I will never use this product again. I clearly had an allergic feaction and I don't think this product is safe to consume through the skin. I also believe the stylist put too much of the product on my hair and I was exposed to high amounts of formaldehyde which caused my hody to have a reaction. Brazilian Blowout should be banned in the US like it is in other ROW countries.

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

none

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

Race: White

Medical Conditions: none

Allergies: NKDA

Important Information:

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

RX Meds: none

OTC Meds: none

Primp Salon 4325 Glenwood Ave. Raleigh, North Carolina 27612

To Whom It May Concern:

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

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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

U.S. Department of Health and Human Services

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

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Form Approved: ON B	See OMB statement	6:10/31/08 on reverse.

		FDA USE ONLY	at
	Triage unit sequence #		
		071538	
J	CT(S)		

1. Patient Identifier 2. Age at Time of Event, or 3 Sex 4. Weight Date of Birth:	1. Name, Strength, Manu	ifacturer (from or	THE RESERVE OF THE	
Female Ib			oduct label)	
l er	#1 Keratin Hair	Treatment		
In confidence Male or kg	#2			110
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	2. Dose or Amount	F	requency	Route
Check all that apply:	#1			
1 Adverse Event Product Problem (e.g., defeats/malfunctions)	1 "		-	
Product Use Error Problem with Different Manufacturer of Same Medicine	#2			
2. Outcomes Attributed to Adverse Event (Check all that apply)	3. Dates of Use (If unkno	wn, give duration)	from/to for 5 Event	Abated After Use
☐ Death: ☐ Disability or Permanent Damage	best estimate)	m, grounding		ped or Dose Reduced
(mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect	#1		#1 🔲	Yes No Do
Hospitalization - initial or prolonged Other Serious (Important Medical Events)	#2		#2 □	Yes DNo DO
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	4. Diagnosis or Reason	for Use (Indication)	Reappeared After
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)	#1		Reint	roduction?
10/06/2015	#2		#1	Yes No Doe App
5. Describe Event, Problem or Product Use Error	6. Lot #	7. Expiration D	Date #2 T	Yes DNo DDoe
Reaction to product. Product is distributed by GH	41	#1	#2 🗀	Tes LINO LI App
hair in FL	#2	#2	9. NDC	or Unique ID
	E. SUSPECT MED 1. Brand Name	ICAL DEVICE		
	2. Common Device Name	9		
	3. Manufacturer Name, C	ity and State		
9				
1	4. Model #	Lot#		5 Operator of Device
	4. model w	201 #		Health Profession
	Catalog #	Expirati	on Date (mm/dd/yyyy)	Lay User/Patien
				Other:
	Serial #	Other #		Officer.
	6. It Implanted, Give Date	(mm/dd/yyyy)	7. If Explanted, Gir	ve Date (mm/dd/yyyy)
			1	
	8. Is this a Single-use De	vice that was Rep	rocessed and Reuse	d on a Patient?
	9. If Yes to Item No. 8, Er	ter Name and Ad	dress of Reprocessor	
		nar radine one rie	or or richiocoso	
6. Relevant Tests/Laboratory Data, Including Dates				
	F. OTHER (CONC	OMITANT) ME	DICAL PRODUC	TS
	Product names and then	apy dates (exclude	e treatment of event)	
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergles, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)	6.0100000000000000000000000000000000000			
race, pregnancy, amount and accordings, invertigately problems, etc.)	G. REPORTER (Se	ee confidentia	lity section on b	ack)
N. Carlotte	(b) (6)			
	(0) (0)			
	1.00			
	Phone #		E-mail	
A PROPILOT AVAILABILITY	831-524-2855 2. Health Professional?	3 Occupation	d L	Alea Penestad to
C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA)	Yes No	o. Occupation	4	Also Reported to:
TO SEND PRODUCT TO EVALUATION: (DO NOT SEND PRODUCT TO PUA)		a Ideath at		☐ Manufacturer☐ User Facility
Yes No Returned to Manufacturer on:	5. If you do NOT want you	ur identity disclos	ed	Coci i acility

Peter Coppola Heaquarters 7000 W. Camino Real, Suite 200 Boca Raton, Florida 33433

To Whom It May Concern:

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

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To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 192574.

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

BRAZILIAN BLOWOUT 28001 DOROTHY DR AGOURA HILLS, California 91301

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Center for Food Safety and Applied Nutrition

Internet Consumer Report

Form Approved OMB No. 0910-0291. Expires 06/30/2018 See PRA statement on reverse

MEDWATCH

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

	FDA USE ONLY	
Triage unit sequence #	454382	
FDA Rec		

The FDA Safety Information and Adverse Event Reporting Program

Note: For date prompts	Committee of the commit		day, 3-letter m	nonth	3. Dos	se or Amount	Frequency		Route	
abbreviation, and 4-digi		01-Jul-2015,			#1				-	
A. PATIENT INFO	The second second		ظرحار	14 106 7-54	N L					
Patient Identifier 2.		=	3. Sex	4. Weight	#2					
21	Week(s)	Day(s)	Female	140	// // // // // // // // // // // // //					
Of	Date of Birth (e.g.,	08 Feb 1925)		V Ib	4 Dates	of Use (From/T	o for each) (If	unknown	O Event	Abated After Use
In Confidence			☐ Male	☐ kg	give a	luration, or best of	estimate) (dd-r	nmm-yyyy)		ed or Dose Reduced
5.a.Ethnicity (Check	5.b.Race (Chec.	k all that apoly)			1000000	pr-2016 -			#1 []	Yes V No Doe
single best answer)			and the latest to	Carton	#2		A W # #	4-4		appl Doe
Hispanic/Latino		American India				osis or Reason	for Use (indic	ation)	#2 Y	es No appl
E Marin or ave	-	rican American	Whit	te	#1					t Reappeared After roduction?
Not Hispanic/Latin		ailan or Other Pa	scific Islander							The state of the s
B. ADVERSE EVE	NT, PRODUCT	PROBLEM			#2				#1 Y	es ☐ No ☑ Doe appl
1. Check all that apply	у				6. Is the	Product	7. Is the Pro	duct	#2 TY	es No Doe
✓ Adverse Event	Product Prob	lem (e.g., defect	s/malfunctions))	Comp	ounded?	Over-the	Counter?		appl
Product Use Erro	r Problem with	Different Manuf	acturer of Sar	me Medicine	#1 🗆 Y	es No	#1 Y	No No		
					#2 🗍 🦠	es No	#2 Y	es No		
2. Outcome Attribute	d to Adverse Event	(Check all that a	pply)		B Expira	tion Date (dd-mi	mm-yyyy) #			#2
Death Include dat	te (dd-mmm-yyyy) _			tin d	E SI	SPECT MED				
Life-threatening		Disability	or Permanent I	Damage	1. Brand		DEV			MAY -5 201
Hospitalization - in	Control of the contro		Anomaly/Birth	h Defects						Mary
The second of th	portant Medical Ever	Contract of the contract of th	4077							MAY - 5 201
Required Interven	tion to Prevent Perm				2. Comm	on Device Nam	e			2b. Procode
3. Date of Event (dd-n	nmm-yyyy)	4. Date of this	Report (dd-mr	mm-yyyy)	2 11		214			
11-Apr-2016		04-May-201	6		3. Manut	acturer Name, (ity and State			
F Danadha Frant Da	thing on Decision 1	F			+					
 Describe Event, Pro See additional 	A CANADA TA MANAGA MANAGA				4. Model	1#	Lot#			5. Operator of Device
Dec addresonas	page (3) for c	omprete ter					1			S. S. Politico, S. Politico
					1					Health Profession
					Catalog	#	Expirati	on Date (dd-n	nmm-yyyy	Lay User/Patien
Relevant Tests/Labo	oratory Data, Includ	ing Dates			1		1-2-3			
					13.70					☐ Other
					Serial f	*	Unique	Identifier (UD)I) #	
							1			
 Other Relevant Histories, pregnancy, 	ory, Including Prees smoking and alcoho	xisting Medical ol use, liver/kidne	Conditions (e. v problems, etc	.g.,						
See additional p	the facility of the contract of	and a second and a second			6. If Impl	anted, Give Dat	e (dd-mmm-yy	(yy) 7. If Exp	lanted, G	ive Date (dd-mmm-yy
					8. Is this	a single-use de	evice that was	nt?	Yes [Na
. PRODUCT AVA	II ABILITY	V - W	- 5	-	10000	to Item 8, Enter N			essor	
2. Product Available fo		ot send product	o FDAJ			19,941,111,11	1995 HOLD 1800	220-2120-2	22116	
✓ Yes No										
E 140	L. Metallied to Mi	analacidici uli -	(dd-mmm-)	yyyy)	F. OT	HER (CONC	OMITANT	MEDICAL	PRODI	JCTS
D. SUSPECT PR	ODUCTS			1		names and the				
Name, Manufacturer							and the second			
#1 - Name and Strength keratin cure cho			# or Unique II	D		PORTER (Se	e confident	ality section	i on bac	K)
The same of	The state of the s				Last Nar	and Address		First Nan	ne (b) (6	
					Address				- 44	
#1 - Manufacturer/Comp	pounder	#1- Lot #			City:			State/Provi	nce/Regio	n
Keratîn Cure										
#2 - Name and Strength	h	#2 400	# or Unique IE	7	Country:			- I - N	Postal C	ode:
re-iname and Strength		#2 - NDC	# or Onique IL		Phone #:		E-m	ail:		
					2. Health	Professional?	3. Occupatio	n	12	Also Reported to:
#0 Max 4- 1-	a a consider	un to			□ Y	es No				Manufacturer/
#2 - Manufacturer/Comp	bonuaer	#2- Lot #			1					Compounder
						do NOT want y			3. 1118	User Facility
		-			to the	manufacturer,	please mark t	his box:	C 10	Distributor/Importe

FORM FDA 3500 (10/15)

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



654302

8.5. Describe Event or Problem (continued)

I ordered a keratin hair treatment from keratincure.com and wasn't aware that it had formaldehyde in it. When I used the treatment it gave me respiratory problems and burned my eyes.

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

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

Medical Conditions: n/a

Allergies: n/a

Important Information:

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

Internet Consumer Report

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

MEDWATCH

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

	FDA USE ONLY	
Triage unit sequence #	454382	
FDA Rec		

The FDA Safety Information and Adverse Event Reporting Program

Note: For date prom- abbreviation, and 4-				day, 3-letter n	nonth		se or Amount	Frequency	I F	oute	
A. PATIENT IN			1-Jul-2015,	-	2027	#1					
Patient Identifier		✓ Year(s)	Month(s)	3. Sex	4. Weight						
) (6)	28	Week(s)	=		140	#2					
In Confidence	or Date	of Birth (e.g.,	08 Feb 1925)	Female Male	✓ lb	give	s of Use (From/T duration, or best	o for each) (If un estimate) (dd-mr	iknown. nm-yyyy)		Abated After Use ed or Dose Reduce
5.a.Ethnicity (Chec single best answer)		b.Race (Check	k all that apply)			#1 11-	Apr-2016 -			#1 🔲 ۱	res ✓ No ☐ Do
Hispanic/Latin	- 1	Asian	American India	n or Alaskan t	Native	5. Diag	nosis or Reason	for Use (indicat	ion)	#2 🗌 Y	es No Do
Not Hispanic/L	L		ican American alian or Other Pa	White	te	#1	aightens hair				Reappeared After roduction?
B. ADVERSE E	VENT.	_				#2				#1 🗌 Y	es No Vap
1. Check all that a	pply					6. Is the	Product	7. Is the Prod	luct	#2 Y	es DNo DDo
Adverse Even	t 🗸	Product Probl	em (e.g., defect	s/malfunctions,)		pounded?	Over-the-C			app
Product Use E	rror 🔲	Problem with I	Different Manuf	acturer of Sar	me Medicine			#1 V Yes			
2. Outcome Attrib	uted to A	dverse Event	(Check all that a	pply)		#2 D	Yes No ation Date (dd-mi	#2 Yes	□ No		ūz.
Death Include			The second second								#2
Life-threatenin	Section 1	3000	Disability	or Permanent	Damage	1. Bran	JSPECT MED	ICAL DEVIC	,E		10.17
Hospitalization Other Serious		100000		l Anomaly/Birt	h Defects	, Gran	u Name				MAY -5 20
Required Inter	vention to	Prevent Perm	anent Impairmer	The state of the s		2. Com	mon Device Nam	ie			2b. Procode
3. Date of Event (co. 11-Apr-2016	ld-mmm-y	מממ	4. Date of this		тт-уууу)	3. Manu	ıfacturer Name, (City and State		_	
			March 19	. 0		1					
5. Describe Event, See additiona		F. 71 . 12 . 12 . 12 . 1		it.		4. Mode	al #	Lot#			5. Operator of Dev
Relevant Tests/L	aborator	y Data, Includi	ing Dates			Catalog)#	Expiration	Date (dd-mn	пт-уууу)	Lay User/Patie
											Other
						Serial	#	Unique lo	lentifier (UDI)	#	
Other Relevant H allergies, pregnan See additiona	ncy, smok	ing and alcohol	use, liver/kidne	y problems, etc	.g., c.)	6. If Imp	planted, Give Dat	e (dd-mmm-yyy	7. If Expla	inted, G	ive Date (dd-mmm-)
						8. Is thi	s a single-use de ocessed and reus	evice that was	2 []	Yes [No
. PRODUCT A			at a and product	e EDAL		10000	to Item 8, Enter N			ssor	
✓ Yes □ N			nufacturer on:			1.					
D. SUSPECT F			and draw and	(dd-mmm-)	yyyy)		THER (CONC t names and the				
1 - Name and Stren	igth		#1 - NDC	# or Unique I	D		PORTER (Se	e confidentia	lity section (on back	()
Care Care	-110-601-6	are man vi					e and Address		First Name	(D) (6	
						Address	S				
1 - Manufacturer/C	ompound	er	#1- Lot #		_	City:			State/Provinc	e/Region	16
Geratin Cure											
#2 - Name and Stre	ngth		#2 - NDC	# or Unique It	D	Phone #		E-mai	1.75	Postal Co	ode:
			1 67			Prione #		E-mai			
			1			2. Healt	h Professional?	3. Occupation		al e	
2 - Manufacturer/C	ompound	er	#2- Lot #	0 0		1000 1000 1000	res No				Also Reported to: Manufacturer/ Compounder
							do NOT want y			1	User Facility
			- 1			to the	e manufacturer,	please mark thi	s box:		Distributor/Impor

FORM FDA 3500 (10/15)

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654302

8.5. Describe Event or Problem (continued)

I ordered a keratin hair treatment from keratincure.com and wasn't aware that it had formaldehyde in it. When I used the treatment it gave me respiratory problems and burned my eyes.

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

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

Medical Conditions: n/a

Allergies: n/a

Important Information:

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





July 21, 2016

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

Re: CAERS# 196079

We are in receipt of your letter dated June 29, 2016. This is the first time that we have received any complaint about our product "Keratin Cure Chocolate Max V1". However, we are open to be in touch with you about this case and any future information thereof.

Thank you for the opportunity to help us with this issue.

Regards,
Mourad Ramoul
C.E.O

CORPORTOR

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CORPORTOR

CORPOR

'16 JL ₩

3406 Northwest 151 Terrace
Miami Gardens, Florida 33054 USA
T: (305) 406-1022 . F: (305) 591-7964
www.keratincure.com

BEAUTY COSMETICA 3406 NW 151 Terrace Miami Gardens, Florida 33054

To Whom It May Concern:

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

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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

MEDWATCH

PLEASE TYPE OR USE BLACK INK

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

Internet Consumer Report

	FDA USE ONLY	
Triage unit sequence #	1057542	
FDA Rec.		
Date		

The FDA Safety Information and Adverse Event Reporting Program
Note: For date prompts of "dd-mmm-yyyy" please use abbreviation, and 4-digit year; for example, 01-Jul-201
abbreviation, and 4-digit year, for example, 01-Jul-201

Note: For date promp	ts of "dd-mmm-yyyy"	please use 2-digit	day, 3-letter n	nonth	3. D	ose or Amount	Frequency		Route		
abbreviation, and 4-di		, 01-Jul-2015.			#1				Lopisal		
A. PATIENT INF											
1. Patient Identifier (b) (6)	2. Age Year	=	3. Sex	4. Weight	#2						
In Confidence	or Date of Birth (e.) (b) (6)	q. 08 Feb 1925)	Male Male	✓ lb	give	es of Use (From/ duration, or best	estimale) (dd-m	nknown, mm-yyyy)		t Abated Aft ped or Dose	
5.a.Ethnicity (Check	5.b.Race (Che	eck all that apply)			#1 01	-May-2012 - 18-	May-2016		#1 🗌	Yes No	Doesn't
single best answer)	☐ Asian	American India	an or Alaskan N	Native	277-0	nosis or Reasor	for Use (indica	tion)	#2 🗍	Yes No	Doesn't
☐ Hispanic/Latino Not Hispanic/La		African American	While	te	#1 in	salon smoothin	g treatment			nt Reappeare	ed After
B. ADVERSE EV	INDINCE LIE	0.0000000000000000000000000000000000000	acine Islander		#2				#1 🗸	Yes No	Doesn't apply
1. Check all that app	The state of the s	TINOBELIII			O to the	- Doesdood	In Car w		#2 🗖	Vac Data	Doesn't
✓ Adverse Event		blem (e.g., defect	s/malfunctions			e Product pounded?	7. Is the Prod Over-the-C		#2 []	Yes No	apply
Product Use Em		h Different Manuf			#1 🔲	Yes V No	#1 🗸 Ye	□ No			
					#2 []	Yes No	#2 🗌 Ye	s No			
2. Outcome Attribut	ted to Adverse Ever	nt (Check all that a	(pply)		8. Expir	ration Date (dd-m	mm-yyyy) #1			#2	
☐ Death Include d ☐ Life-threatening ☐ Hospitalization - ✓ Other Serious (III		☐ Disability ☐ Congenita	or Permanent	h Defects	STATE OF THE PARTY	USPECT MEI	DICAL DEVI	CE			
	ention to Prevent Per	The state of the s			0.00	mon Device Nan		- (3711	ton Dunnard	
3. Date of Event (dd	A STATE OF THE SAME	4. Date of this	1.200		2. Com	imon Device Nar	ne	- Control		2b. Procod	е
18-May-2016		19-May-20		>>>>	3. Man	ufacturer Name,	City and State	MAY	2 0 20	16	
5. Describe Event, P	roblem or Product	Use Error				- 13:	11.44				
See additional	page(s) for	complete tex	C.		4. Mod	el#	Lot#			5. Operato	r of Device
										☐Health	Professional
					Catalo	g#	Expiratio	n Date (dd-i	mm-vvv		ser/Patient
6. Relevant Tests/Lal	boratory Data, Inclu	iding Dates						re-e-r	200	Other:	
					122					U Other.	
					Seria	1#	Unique I	dentifier (U	DI) #		
7. Other Relevant His	story, Including Pre	existing Medical	Conditions (e	.g.,							
See additional	y, smoking and alcol page(s) for			2.)	6. If Im	planted, Give Da	te (dd-mmm-yyy	y) 7. If Ex	planted, C	Give Date (de	d-mmm-yyyy)
					8. Is th	is a single-use d ocessed and reu	levice that was ised on a patien	t? [Yes	□ No	-
C. PRODUCT AV 2. Product Available	for Evaluation?(Do	and the second			9. If Ye	s to Item 8, Enter	Name and Addre	ss of Repro	cessor		
✓ Yes No	Returned to	Manufacturer on:	(dd-mmm-)	(MY)	F. O	THER (CONC	COMITANT	MEDICAL	PROD	UCTS	CONT. NO.
D. SUSPECT PR						ct names and the					
1. Name, Manufactur				0	C D	EDORTER /S	as assticiantic	lity anotin	n nn han	161	_
#1 - Name and Streng Brazilian Blows		(#1 - NDC	# or Unique I			EPORTER (S ne and Address	ee connaenue			in)	
1					Last N	ame(b) (6)		First Na	me: (b) (6)		
	7				Addres	35: 405 south 2nd	street				
#1 - Manufacturer/Coi	mpounder	#1- Lot #	7		City(b)	(6)		State/Prov	ince/Remi	on the View	
EBG	V				- my (12)	, (9)		Calculation.	yii	(a) (a)	
	216	00 000	4		Countr	y; us		ZI	P/Postal C	Code(b) (6)	
#2 - Name and Streng	gui	#2 - NDC	# or Unique It	,	Phone		(b) (6			100	
					(b)	(6)	(w) (c				
						th Professional?	3. Occupation		14	Also Repo	rted to:
#2 - Manufacturer/Cor	mpounder	#2- Lot #				Yes No				Manufac	
	- Postiani	,,2 ,501 #		7.47		u do NOT want y			1	Compou	
	79 201 201				7.77			Daniel C			- importor

I am a salon professional who is working in a salon that provides Brazilian blowout services in an non ventilated space and insufficient training in application of this product. I have been exposed to formaldihyde fumes that have caused me eye burning, migraine, dizziness, and now a lasting burnt and sore nasal passage and throat.

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

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

Medical Conditions:

Allergies:

Important Information:

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

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

	FDA USE ONLY	
Triage unit sequence #	10.57542	
FDA Rec.		
Date		

	TION						- 11			
FORMA		- Dwarf (*)		Id Weight						
z. Age	☐ Year(s) ☐ Week(s)			128	#2	7				
		08 Feb 1925]	- N. C.	☑ lb	4 De	tes of Use /Fro	m/To In	or each) (If unkno	own lo Fue	ent Abated After I
(0) (0)		Male	☐ kg					yyyy) Sto	opped or Dose Re
k 5.b	Race (Check	(all that apply)			1	1-May-2012 -	18-May-	-2016	#1	Yes V No
	Asian	American India	n or Alaskan N	Native.	200	agnosis or Reas	son for	r Use (indication)	#2	Yes No
, 15			and the second second second		1					ent Reappeared A
atino	Native Hawa	alian or Other Pa	cific Islander		10,					introduction?
VENT. P	1163343130	en district de district		- 4	#2				#1 🗸	Yes No
ply					6. Is 1	he Product	17	7. Is the Product	#2 [Yes No F
□ Pr	oduct Proble	em (e.g., defects	s/malfunctions))					The second second	
rror Pr	oblem with I	Different Manuf	acturer of Sar	ne Medicine	#1 [Yes V N	0	#1 🗸 Yes	□ No	
ited to Ad	orea Evert	Chack all that a	nolul		#2 [#2 Yes	□ No	
		Check all that a	pply)					Total Control		#2
	mm-yyyy): _	☐ Disability	or Permanent I	Damage			EDIC	AL DEVICE		
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vention to F	revent Perma	anent Impairmer	nt/Damage (De	evices)	2. Co	mmon Device I	Vame	-	GTU	2b. Procode
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	(b) (b) (c) (c) (d) (d) (d) (d) (d) (d) (d) (d) (d) (d	Week(s) or Date of Birth (e.g., (b) (6) K 5.b,Race (Check Asian Black or Africatino Native Haway VEN'F, PRODUCT Problem With Interest of the Adverse Event Interest of The Interest o	Week(s) Day(s) or Date of Birth. (e.g., 08 Feb 1925) (b) (5) K 5.b.Race (Check all that apply) Asian American India Black or African American atino Native Hawaiian or Other Pa VENT, PRODUCT PROBLEM or Product Problem (e.g., defects from Problem with Different Manuf. atited to Adverse Event (Check all that a date (dd-mmm-yyyy): I Disability of Indian Important Medical Events) migrane, burn rention to Prevent Permanent Impairment d-mmm-yyyy) 4. Date of this 19-May-201 Problem or Product Use Error	Week(s) Day(s) Female Week(s) Day(s) Female Week(s) Day(s) Female Week(s) Day(s) Female Week(s) Female Week(s) Wale Male Week(s) Week(s)	Week(s) Day(s) Temale I b Walls Walls	Week(s) Day(s) 128 #2	Week(s) Day(s) Female 128 #2	Week(s) Day(s) Je Female Je Je Je Je Je Je Je	Week(s) Day(s) 7 Female 128 15 16 16 16 16 16 16 16	Week(s) Day(s) Pemale I 28 I 28

I am a salon professional who is working in a salon that provides Brazilian blowout services in an non ventilated space and insufficient training in application of this product. I have been exposed to formaldihyde fumes that have caused me eye burning, migraine, dizziness, and now a lasting burnt and sore nasal passage and throat.

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

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

Medical Conditions:

Allergies:

Important Information:

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

Internet Consumer Report

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

adverse events, product problems and product use errors

For VOLUNTARY reporting of CF5UL verse events, product excel FDA USE ONLY Triage unil sequence # FDA Rec.

MEDWATCH The FDA Safety Information and

PLEASE TYPE OR USE BLACK INK

Adverse Event P	Reporting Program						Date			
Note: For date promp	pts of "dd-mmm-yyyy" pleas	e use 2-digit	day, 3-letter m	onth	3. D	lose or Amount	Frequency		oute	
	digit year; for example, 01-J	ul-2015.			#1				pplied to	o a surface, usually
A. PATIENT IN				التيور				- IE		
1. Patient Identifier	2. Age ✓ Year(s)	Month(s)	3. Sex	4. Weight	ll T					
(0) (0)	30 Week(s)	Day(s)		115	#2					
	or Date of Birth (e.g., 08 F	eb 1925)	Female	✓ lb						
			☐ Male		4. Dat	es of Use (From/Te duration, or best of	o for each) (If u	nknown, 9		Abated After Use
In Confidence				☐ kg		5-Apr-2016 - 16-A		The second second		ed or Dose Reduced?
5 a Ethnicity (Chec single best answer)	5.b.Race (Check all	that apply)			#2				*1 × Y	esapply_
	Asian Ar	nerican India	n or Alaskan N	lative		gnosis or Reason		tion)	#2 Y	es No Doesn't
Hispanic/Latino	Black or African	American	✓ Whit	е	#1 Ha	iir smoothing tre	atment	1	0.Event	Reappeared After
Not Hispanic/L	atino Native Hawaiiar	or Other Pa	cific Islander		100					oduction?
B ADVERSE F	VENT, PRODUCT PR	Control Annual Control		-	#2				#1 Y	es No Doesn't
1. Check all that ap		CODELIN		_	1				т П.	-
Adverse Event		uses have an			100	ne Product	7. Is the Pro Over-the-		F2 L Y	es No Doesn't
		The state of the s			#1 []	- FR 44	#1 7 Ye			
Product Use E	rror Problem with Diffe	erent Manut	acturer of San	ne Medicine	_					
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	date (dd-mmm-yyyy):	Car and The	1045			ration Date (dd-mi	saise al		*	¥2
	T.	Disability of	or Permanent I	Damage		USPECT MED	ICAL DEVI	CE		
Life-threatening	g - initial or prolonged		Anomaly/Birth		1. Bra	nd Name				
	Initial or prolonged [(Important Medical Events)	_ congenita	. anomaly on t	, Dorona						
	vention to Prevent Permane	nt Impairmen	//Damage (De	vices)	0.0	B. C. N.			-	N. B. C. L.
3. Date of Event (d			Report (dd-mn		2. Con	nmon Device Nam	е			2b. Procode
Annual Control of the Control	2		The Control of the	33337	3. Mar	ufacturer Name, (City and State	So.		CTU
16-Apr-2016	28	-May-201	.6							000
5. Describe Event,	Problem or Product Use E	rror							8.4	AV 27 2016
See additiona	al page(s) for comp	lete tex	t.		4. Mod	del #	Lot#		l/o	6. Operator of Device
					Catala	- #	-			Health Professional
6. Relevant Tests/L	aboratory Data, Including	Dates		_	Catalo	og #	Expiration	n Date (dd-mm	т-уууу)	Lay User/Patient
	1 page(s) for comp		t,							Other:
	7-7-20-1									
					Seria	1 #	Unique	dentifier (UDI)	#	
7. Other Relevant H	listory, Including Preexisti	ng Medical	Conditions (e.	g.						
allergies, pregnan	icy, smoking and alcohol use	, liver/kidney	problems, etc	:)	B 16 to	planted, Give Dat	e /dd-mmm-yy	W 17 If Expla	nted. Gi	ve Date (dd-mmm-yyyy)
See additional	L page(s) for comp.	lete text			0. 17 111	ipianteu, Give Dat	e (do-mini-yy)	92		
					8 is ti	nie a single-use de	wire that was			
					rep	nis a single-use de rocessed and reus	ed on a patier	it?	Yes	No
C. PRODUCT A	VAILABILITY				9. IF Y	es to Item 8, Enter N	lame and Addr	ss of Reproces	sor	
2. Product Available	e for Evaluation?(Do not se	end product t	o FDA)							
Yes N	Returned to Manuf	acturer on: -		_						
h-1	THE WALL PARKS	G 27 (G)	(dd-mmm-y	yyy)		THER (CONC				
D. SUSPECT F					Produ	ct names and the	rapy dates (Ex	clude treatment	of event	()
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	wout Acai Professi		a an arringues in	6	1. Nar	ne and Address	5 50/M55/M			
					Last	Varne. (b) (6)		First Name	(b) (6)	
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#1 - Manufacturer/Co	The second secon	#1- Lot #			City			State/Province	e/Region	i:
Brazilian Blow	WOLL					-				
#2 - Name and Street	nath	#2 - NDC	# or Unique ID)	Count		TYPE		ostal Co	ode
Traine and odd		100	s. amque to		Phone	#:	E-ma	aut:		
		1				Ith Professional?	3. Occupation	1	14.	Also Reported to:
#d 14		WO 1 - 1 - 1				Yes No			Г	Manufacturer/
#2 - Manufacturer/C	ompounder	#2- Lot #								Compounder
						ou do NOT want y			L	User Facility
					tot	he manufacturer,	please mark th	is box:		Distributor/Importer
		1								

Got a Brazilian Blowout in the afternoon. Got an acute headache immediately after and felt fatigued and dizzy for about a week after the procedure. I also had a sore mouth and throat, it felt as if my entire mouth had been burned, for about a week after. On the third night after receiving the procedure, I had insomnia, my heart started racing and I was shaking. I felt as if my body had been poisoned.

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: Sulfa drugs

Important Information: None

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

RX Meds: Ciclopirox topical cream

OTC Meds; None

Internet Consumer Report

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

For VOLUNTARY reporting of CF5404 adverse events, product problems and product use errors

FDA USE ONLY Triage unil sequence # FDA Rec.

MEDWATCH The FDA Safety Information and

PLEASE TYPE OR USE BLACK INK

Adverse Event Reporting Program	1				Date				
Note: For date prompts of "dd-mmm-yyyy" ple	ease use 2-digit d	lay, 3-letter m	onth	3. Dose or Am	ount Frequency	1	Route		
abbreviation, and 4-digit year; for example, 0 A. PATIENT INFORMATION	1-Jul-2015.			#1			Applied to the skin	a surfac	ce, usually
1. Patient Identifier 2. Age Year(s)	Month(s)	3. Sex	4. Weight						
30 Week(s)	Day(s)	▼ Female	115	#2					
or Date of Birth (e.g.,)	08 Feb 1925)		✓ lb	4 Dates of Use /	From/To for each) //f	unknown	9. Event A	hated Aft	er Use
In Confidence		Male	☐ kg		From/To for each) (If or best estimate) (dd-r	nmm-yyyy)			Reduced?
5.a Ethnicity (Check 5.b.Race (Check	(all that apply)			#1 16-Apr-2016	- 16-Apr-2016		#1 🗸 Ye	s No	Doesn' apply
single best answer)	American Indian	or Alaskan N	lative		Reason for Use (indic	ation)	#2 Ye	s No	Doesn' apply
Hispanic/Latino Black or Afric	can American	✓ Whit	е	#1 Hair smooth:	ing treatment		10.Event F		ed After
✓ Not Hispanic/Latino Native Hawa	alian or Other Pac	ific Islander					-	duction?	No.
B. ADVERSE EVENT, PRODUCT	PROBLEM			#2			#1 Ye	s No	apply
1. Check all that apply				6. Is the Product		oduct	#2 🗌 Ye	s No	Doesn' apply
✓ Adverse Event Product Proble	em (e.g., defects/	malfunctions)		Compounded?		-Counter?	-		арріу
Product Use Error Problem with D	Different Manufa	cturer of San	ne Medicine		No #1 ✓ Y				
2. Outcome Attributed to Adverse Event	(Check all that ap	ply)		#2 Yes B. Expiration Date	1000	es No		2	
Death Include date (dd-mmm-yyyy):					4,777		#2		
Life-threatening	☑ Disability or	Permanent [Damage	1. Brand Name	MEDICAL DEV	ICE			
Hospitalization - initial or prolonged	Congenital.	Anomaly/Birth	Defects	The state of the s					
Other Serious (Important Medical Event	The section of the se	Damage /Da	vices\						
	4. Date of this R			2. Common Devi	ce Name		2	. Procod	e
		To Control of the		3. Manufacturer I	Name, City and State			CTL	1
16-Apr-2016	28-May-2016	0'						000	
5. Describe Event, Problem or Product Us				4. Model #	Lot#		杨春	I Bady	711h or of Device
See additional page(s) for co	omplete text				1 5000			. Operato	I Of Device
								Health	Professional
3. Relevant Tests/Laboratory Data, Includi	ng Dates			Catalog #	Expirati	on Date (dd-r	ттт-уууу)	Lay U	ser/Patient
See additional page(s) for co								Other:	
				Serial #	Unique	Identifier (UI	DI) #		
				Serial W	Onique	identinei (di	Ji) #		
 Other Relevant History, Including Preex allergies, pregnancy, smoking and alcohol 									
See additional page(s) for co				6. If Implanted, G	ive Date (dd-mmm-y	yy) 7. If Exp	planted, Giv	e Date (de	d-mmm-yyyy,
				0 to this a single	una davina that was		_		
					-use device that was nd reused on a patie		_	No	
C. PRODUCT AVAILABILITY	No. Land	C. A.		9. If Yes to Item 8,	Enter Name and Add	ress of Repro	cessor		
2. Product Available for Evaluation? (Do no		FDA)							
Yes No Returned to Ma	nufacturer on: -	(dd-mmm-y	(VVV)	F OTHER	CONCOMITANT	MEDICAL	PRODU	CTS	
D. SUSPECT PRODUCTS		7	144/	Product names a	and therapy dates /E	clude treatme	ent of event)		
Name, Manufacturer/Compounder, Street		rct label) # or Unique II		The state of the s	I page(s) for co	A DECEMBER OF			_
Fi-Name and Strength Brazilian Blowout Acai Frofes		e or unique II	0	1 Name and Add	R (See confident tress				
The state of the s				Last Name: (b)	(6)	First Na	me (b) (6	5)	
				Address:		No.			
#1 - Manufacturer/Compounder	#1- Lot #		_	City		IState/Provi	ince/Region:		
Brazilian Blowout	177					S.a.c.	co.rsegion.		
#7. Name and Street	UN 1100	Lab Halanda		Country:		ZII	P/Postal Cod	le	
#2 - Name and Strength	#2 - NDC #	f or Unique ID		Phone #:	E-n	nail:			
				10000	عاللت فيست				
	11/4				sional? 3. Occupation	on	4. 4	Also Repo	
#2 - Manufacturer/Compounder	#2- Lot #			Yes N	0			Manufa Compoi	
4 4 4 4 3 5 4 4 4 5 6 4 4 4 4 5 6 4 4 4 4 4 4 4 4				5. If you do NOT	want your identity d	isclosed		User Fa	
					cturer, please mark			Distribut	or/Importer
CODM EDA SEGO (40/4E) Summir	make of a sunnel s	feng and poor	this se set	that median	harmanial at the nea	diret aniiphala	or excellent the	d to them	Conf

Got a Brazilian Blowout in the afternoon. Got an acute headache immediately after and felt fatigued and dizzy for about a week after the procedure. I also had a sore mouth and throat, it felt as if my entire mouth had been burned, for about a week after. On the third night after receiving the procedure, I had insomnia, my heart started racing and I was shaking. I felt as if my body had been poisoned.

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: Sulfa drugs

Important Information: None

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

RX Meds: Ciclopirox topical cream

OTC Meds; None

BRAZILIAN BLOWOUT 28001 Dorothy Dr Agoura Hills, California 91301-2609

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 196901.

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

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

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

	FDA USE ONLY
Triage unit sequence #	6/0/0273
FDA Rec	
Date	

MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

								Land			
Note: For date prom				day, 3-letter in	nonth	13.	Dose or Amount	Frequ		Route	my hair with it
abbreviation, and 4-			-Jul-2015.			#1	2 Ounce(s)	Once	a day	Washed	my marr with it
A. PATIENT IN	IFORMATI	ON		1							
Patient Identifier	2. Age	Year(s)	Month(s)	3. Sex	4. Weight						
(6) (6)		Week(s)	Day(s)		144	#2					
	or Date of B	irth (e.g., 08	3 Feb 1925)	Female	[7] lb						
In Confidence	(b)			☐ Male	☐ kg		tes of Use (From/) ve duration, or best 6-Jun-2016 - 03				ent Abated After Use opped or Dose Reduced?
5.a.Ethnicity (Chec single best answer)		ice (Check a	all that apply)			#2				#1	Yes No Doesn't
	ITA	sian 🗍	American India	n or Alaskan N	Vative	100	agnosis or Reason	for Use	(indication)	#2	Yes No Doesn't
☐ Hispanic/Latin	В		an American	☑ Whit	te	#1 s	moothing for hair				ent Reappeared After introduction?
E .			an or Other Pa	icitic Islander	-	#2				#1 17	Yes No Doesn't
B. ADVERSE E		ODUCTE	ROBLEM	1 × ×	100					- 1	арріу
1. Check all that a	All the same of						he Product	14 0 144	ne Product	_	Yes No Doesn't apply
✓ Adverse Even			n (e.g., defects				mpounded?		r-the-Counte	27 5 2 7 10	
Product Use E	rror Prob	lem with Di	fferent Manuf	acturer of San	ne Medicine	-	Yes No	-	✓ Yes	No	
2. Outcome Attrib	inted to Adver	se Event (C	heck all that a	nnlv)			Yes No	#2		No.	
			TO SIL GIL ALIGN D	PPUI			iration Date (dd-m.	100	11.1	المتنا	#2
Death Include	4.4	п-уууу):	Disability	or Permanent I	Damage	E. 5	SUSPECT MED	DICAL	DEVICE		
Life-threatenin		and a		Anomaly/Birth		1. Bra	and Name				
☐ Hospitalization ☐ Other Serious				Allomalyrum	ii Delecia						
Required Inter	Acres de la companya del la companya de la companya			t/Damage (De	vices)	0.0-	mmon Device Nam				los posses
3. Date of Event (o	200000000000000000000000000000000000000		. Date of this	The second second	11.50	2. 00	mmon Device Nam	1e			2b. Procode
	× 10111111 33337				73727	3. Ma	nufacturer Name,	City and	State	5 Ås 20	- I - Hadi
20-Jun-2016		3	04-Jul-201	6						JUL	-5 2016
5. Describe Event,	Problem or P	roduct Use	Error								a 5010
See additiona	al page(s)	for cor	mplete tex	t.		4. Mo	del#	Lo	ot#		5. Operator of Device
											П.
-						Catal	lon#		an own as an	A Processing at	Health Professional
6. Relevant Tests/L	aboratory Da	ta, Includin	Dates			Catal	log #	Ex	piration Date	(dd-mmm-yy	(yy) Lay User/Patient
See additiona	l page(s)	for com	plete tex	t.				- 12			Other:
						Seri	-14			0.0m (i .ii	
						Seri	ai#	U	ilque Identifi	er (UDI) #	
7. Other Relevant H	listory, Includ	ling Preexis	ting Medical	Conditions (e.	g.,						
allergies, pregnan			The second second second second	The state of the s)	6. If Ir	mplanted, Give Dat	te (dd-mn	nm-yyyy) 7.	If Explanted	Give Date (dd-mmm-yyyy)
See additiona.	1 page(s)	TOT COM	prece text	D.		4.78	A Secretary	4 × 75,530		A Property	
						8, Is t	this a single-use d	evice tha	t was	Yes	Пма
	-					1	rocessed and reu				□ NO
C. PRODUCT A				- 5041		9. If Y	es to Item 8, Enter i	Name and	Address of F	Reprocessor	
2. Product Availabl		200 42 46 20									
✓ Yes □ N	lo Retu	rned to Man	ufacturer on: -	(dd-mmm-y	2000	C.	OTHER (CONC	OMITA	NT MED	CAL DDO	DUCTE
D. SUSPECT P	PRODUCTS	\$		(dd-mmm-y	1111		OTHER (CONC uct names and the				
1. Name, Manufactu			th (from prod	luct label)			additional page				
#1 - Name and Stren		C.A	#1 - NDC	# or Unique II	D		REPORTER (Se	ee confi	dentiality s	ection on ba	ack)
Brazilian blov frig, 12 350 m		anti				1. Na	me and Address Name: (b) (6)	_	TE	st Name (b)	(6)
	Mole	Vi II				1	es (b) (6)	-	100	(D)	(0)
		11				7 10101	(p) (q)				
#1 - Manufacturer/C	ompounder	1	#1-Lot#			City(b) (6)		IState	/Province/Reg	aion:
GIB LLC			994715	D			4.574			23.0.000.000	
						Coun	ntry us		-	ZIP/Posta	Code (b) (6)
#2 - Name and Stre	ngth		#2 - NDC	# or Unique IC		Phone			(b) (6)		
						(b)	(6)		(D) (D)		
						A STATE OF THE PARTY OF THE PAR	alth Professional?	3. Occu	pation		A Alex Deni destac
			4-1			100 000	Yes No	1			4. Also Reported to: Manufacturer/
#2 - Manufacturer/C	ompounder		#2- Lot #		- 6						Compounder
							ou do NOT want y				User Facility
						to	the manufacturer,	please n	nark this box	: [/]	☐ distributor/importer
							VA	_			

I had a Brazilian blowout done on June 16. I have had breathing problems and upset stomach/diarrhea. I went to allergist/asthma dr. My mild asthma had become worse. My breathing test was poor. I was given a breathing treatment, Zyrtec, tested for allergies. I was prescribed a daily inhaler and hasal spray for three months. I have stopped using the Brazilian blowout shampoo and conditioner because this made my symptoms increase. Extremely frustrated and hoping this hasn't done permanent damage.

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

6/22/ 2016 breathing and allergy testing done.

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

Medical Conditions: Mild asthma

Allergies: Sulfa drugs bactruim

Important Information:

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

RX Meds: Trazodone, Zoloft, fluticasone, pro air hfa singular zyrtec

OTC Meds:

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

MEDWATCH

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

	FDA USE ONLY	
Triage unit sequence #	6/0/273	
FDA Rec		
Date		

The FDA Safety Information and Adverse Event Reporting Program

Note: For date prompts of	f "dd-mmm-yyyy" (ilease use 2-digit	day, 3-letter m	onth	3,	Dose or Amount	Frequency	Route	the second secon	
abbreviation, and 4-digit y		01-Jul-2015.		70.00	#1	2 Ounce(s)	Once a day	Washe	d my hair wit	h it
A. PATIENT INFO	-			Lamer		1				
Patient Identifier 2. A		The state of the s	3. Sex	4. Weigh	-					
_	Week(s		✓ Female	144	- #2	the property				
or I	Date of Birth (e.g., (b) (6)	08 Feb 1925)	Male Male	✓ Ib	4. D	ates of Use (From/ ive duration, or best 16-Jun-2016 - 03-	To for each) (If unknow t estimate) (dd-mmm-y		ent Abated Af	Reduce
5.a.Ethnicity (Check	5.b.Race (Chec	k all that apply)			#2	18-000-2014 - 03-	-Ju1-2016	#1 [Yes ✓ No	Do
single best answer)	Asian	American India	n or Alaskan N	lative	100	iagnosis or Reaso	n for Use (indication)	#2	Yes No	□ Do
Hispanic/Latino	Black or Af	rican American	✓ Whit	е	#1	Smoothing for hai	r	10.Ex	rent Reappear	
✓ Not Hispanic/Latino	Native Hav	vailan or Other Pa	cific Islander						eintroduction?	,
B. ADVERSE EVEN	NT, PRODUCT	PROBLEM			#2			#1 5	Yes No	Do
1. Check all that apply					6 Is	the Product	7. Is the Product	#2	Yes No	Do
✓ Adverse Event	Product Prob	lem (e.g., defects	/malfunctions)			ompounded?	Over-the-Count		3,000	□арр
Product Use Error	Problem with	Different Manufa	acturer of San	ne Medici	ne #1 [✓ Yes No	#1 / Yes	No		
20 mm 1 mm 200	_			- 1	#2 [Yes No	#2 Yes	No.		
2. Outcome Attributed			pp(y)		B. Ex	piration Date (dd-r	nmm-yyyy) #1		#2	
Death Include date	(dd-mmm-yyyy): .		or Permanent I	Jamana	E.	SUSPECT ME	DICAL DEVICE			
Life-threatening	at the south of the				1. B	rand Name				
☐ Hospitalization - initi	The state of the s		Anomaly/Birth	Defects						
Required Intervention		The state of the s	VDamage (De	vices)	2.0	ommon Device Na			lob Daniel	
3. Date of Event (dd-mn		4. Date of this i	CTT CTT CTT C	1.4.6	2.00	ommon Device Na	me		2b. Procod	ie
20-Jun-2016		04-Jul-201	16.7.300		3, Ma	anufacturer Name,	City and State	JU	L -5 2011	
5. Describe Event, Prob	lem or Product U	se Error							w rull	G .
See additional p	age(s) for c	complete tex	t.		4. M	odel#	Lot#		5. Operato	or of Dev
									Health	Professi
					Cata	alog#	Expiration Dat	e (dd-mmm-v		
. Relevant Tests/Labora	The state of the s						- April all off a dec	o too tilitili y	Other	
See additional pa	ide(a) for C	ombrece cex	b.,				The state of the s		Other:	9'
					Ser	rial#	Unique Identif	ier (UDI) #		
7. Other Relevant Histor	v. Including Pres	xisting Medical (Conditions /e	a						
allergies, pregnancy, si	moking and alcoho	ol use, liver/kidney	problems, etc	:.)	6 16	Implanted, Give Da	ate (dd-mmm-yand 17	. If Explanter	, Give Date (de	d-mmm-
See additional pa	ige(s) for co	omplete text	D.		J. 11	pranted, Sive Di	The time yyyy	4 1 1 1 1 1 1	100	
					8, Is	this a single-use	levice that was	Yes Yes	□ No	
DDODUCT NAME	ADVITY			33		processed and rei	used on a patient? Name and Address of		П 110	
2. PRODUCT AVAI 2. Product Available for		of send product (n FDA1		9. 11	res to item 8, Enter	reame and Address of	Reprocessor		
Yes No		The second second								
T 103 I NO	☐ vernined to W	anulacturer on: -	(dd-mmm-y	<i>yyy)</i>	F.	OTHER (CON	COMITANT) MED	ICAL PRO	DUCTS	
D. SUSPECT PRO					Prod	duct names and the	erapy dates (Exclude)	treatment of e		-
. Name, Manufacturer/C	ompounder, Stre		uct label) # or Unique II	7			ge(s) for complete See confidentiality s		acki	
razilian blowout	acai anti	W NOC	a or unique it		1 N	ame and Address		**********		
friz, 12 350 ml					Last	Name: (b) (6)	F	irst Name: (b	(6)	
	1.7.7				Add	res (b) (6)				
#1 - Manufacturer/Compo	ounder	#1-Lot#			Chil	b) (6)	ICHAR	e/Province/Re	gion (b) (6)	
GIB LLC		994715			11000	F) (4)	State	- Toylice/Re	Architectural Col	
					Cou	intry US		ZIP/Posta	Code (b)	(6)
#2 - Name and Strength		#2 - NDC	# or Unique ID)	Phor	ne #	E-mail		(0)	(0)
					(b) (6)	(b) (6)	1		
					10000000	ealth Professional	? 3. Occupation		4. Also Repo	orted to:
NE 1840 - 1111						Yes No			Manufa	
HT Blow Facture / Campa	under	#2- Lot #				F to See a			Compo	under
#2 - Manufacturer/Compo										
#2 - Manufacture/Compo							your identity disclose please mark this bo		User Fa	tor/imper

I had a Brazilian blowout done on June 16. I have had breathing problems and upset stomach/diarrhea. I went to allergist/asthma dr. My mild asthma had become worse. My breathing test was poor. I was given a breathing treatment, Zyrtec, tested for allergies. I was prescribed a daily inhaler and hasal spray for three months. I have stopped using the Brazilian blowout shampoo and conditioner because this made my symptoms increase. Extremely frustrated and hoping this hasn't done permanent damage.

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Medical Conditions: Mild asthma

Allergies: Sulfa drugs bactruim

Important Information:

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

RX Meds: Trazodone, Zoloft, fluticasone, pro air hfa singular zyrtec

OTC Meds:

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.

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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

[Close]

FACTS Interface

FACTS Complaint #146492 (CAE	RS #199664)		
Complaint Date	08/01/2016	Complaint Source	Consumer
Accomplishing District	LOS-DO	Complaint Status	Archived
How Received	Phone Call		

Complainant le Name	(b) (6)	Work Phone	(b) (6)
Address	(b) (6)	Home Phone	(b) (6)
	1-7.1-7	Source POC Name	
City	(b) (6)	Source Phone	
State	(6) (6)		
Zip	(b) (6)		
Province			
Country	US		
Mail Code			

Complaint / Injury Complaint Description

In February of 2015, Consumer had a Keratin Complex Hair treatment at a salon. The treatment was left on the scalp for 3 days; the consumer then washed it off at home. She reports hair loss & breakage, hair that felt and looked like a mannequin's hair. She states her eyelashes & hairs in her nose were burnt off and the mucus inside her nose then became pasty. She had red lesions on her legs which itched and then scabbed over. Previous to using the Keratin she had always used Paul Mitchell products to straighten her hair and had no issue with these products. On May 12, 2016 she went back to the salon to have a Brazilian blowout treatment and the salon owner informed her she needed to sign a waiver of liability before the treatment was applied. The Brazilian Blowout is left on for one night only. She also had a reaction to this product and reports extremely dry hair and red lesions on her arms & legs. Complainant states she does not want to sue the salon, but believes she is allergic to something in the formula. She saw a dermatologist approximately one month ago because she thought she was dying of cancer. No diagnosis from dermatologist; however, the doctor believes th side effects she is experiencing are from the formadehyde contained in both products. She has no known allergies and is returning to salon today for a moisturizing treatment and to obtain a list of the ingredients in the product.

	Adverse Event Result	Non-serious Injuries/ Illness
3	Adverse Event Date	2015, 2016
	Notify EIO/EMOPS?	Yes
4	Notification Date	08/01/2016
	Attended Health Professional?	No
	Required Hospitalization?	No
to e	Emergency Room/ Outpatient Visit?	No
	Reported Complaint To?	Other
s	Need Additional/ FDA Contact?	

Remarks

Reported to Panico Salon Owner.

Complaint Symptoms

Symptom Name	Duration	Kemarks
Hair breakage	null null	Hair loss & breakage

NEC - Identify in Remarks null null Red itchy lesions which scab over, burnt eyelashes, pasty nasal mucus

Health Care Professional

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

Duration Remarks

	ı	Proc	luct and	i Labei	ing
--	---	------	----------	---------	-----

Brand Name Brazilian Blowout
Product Name Hair Straightener
FDA Product Code 53ED03

FDA Product Code 53ED03 Qty/Unit UPC Code Package

Exp/Use By Date	Unknown	Lot/Serial	Unknown
Product Used?	Yes	Purchase Date	2015 & 2016
Date Used?	5/12/2016	Amount Consumed/Used	
Amount Remained	N/A	Date Discontinued	
Country of Origin		Imported Product?	No
Retailer Name	Panico Salon	Label Remarks	
		No specific product information provided.	

Manufacturer/Distributor

FEI Name & Address Home District Firm Type

3008575862 Brazilian Blowout 10615 W Vanowen St Burbank CA 91505-1136 LOS-DO Warehouse-Ambient Storage

Initial Evaluation / Initial Disposition

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

Disposition Date 08/05/2016

Remarks

VM left for complainant on 8/1/2016 by CCV requesting additional information. Email sent to complainant on 8/2/2016 at

NUrsitti@aol.com requesting medical information. Will forward to LOS-DO CCC if/when received.

Problem Keyword Details

Reaction red itchy lesions on arms & legs, hair loss, breakage, dry hair, burnt

eyelashes, pasty nasal mucus

Cosmetic			
Cosmetic ID (b) (6)			
DOB		Age	
Gender	Female	Race	
Application Place	Salon/SPA	Reason for Use	Hair Preparations (Non-Coloring)
Application Site	Scalp	Other Products?	
Directions			
Directions Followed?	Yes	Product Duration	
Frequency of Use	Other	Reaction Site	Scalp
Product Use in Off-Label Manner?	No	Off-Label Manner D	esc
Warning Statement on Label?		Warning Statement	s?
Preexisting Conditions?	No	Treatment	
Current Status			
		Medical Treatment	

Adverse Events

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

[Close]

BRAZILIAN BLOWOUT 10615 W Vanowen St Burbank, California 91505-1136

To Whom It May Concern:

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

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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

Triage unit sequence #

MEDWATCH

The FDA Safety Information and

PLEASE TYPE OR USE BLACK INK

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

Page of

Form Approved: OMB No	. 0910-029	1, Expires:1	0/31/08
8	see OMB st	tatement on	reverse

A. PATIENT INF	eporting Program			D. SUSPECT PRODU	ICT/S)		7.0
	2. Age at Time of Event, or	3. Sex	4. Weight	1. Name, Strength, Manufac			
7. Tutterit identifier	Date of Birth:	Female	lb	#1 Brazilian Blowd	the second of th		
In confidence		Male Male	orkg	#2			
	VENT, PRODUCT PRO	BLEM OR ERF	OR	2. Dose or Amount	Frequency		Route
Check all that apply:				1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	riequency		11444
1. Adverse Event Product Use E				#1			
2. Outcomes Attribute (Check all that apply	ed to Adverse Event			3. Dates of Use (If unknown,	give duration) from/to (or	5. Event	Abated After Use
Death: Disability or Permanent Damage			best estimate)	Stopped or Dose Reduced?			
Life-threatening	1000 market and -	ongenital Anomaly/B	7.70	#2		П.	
		ther Serious (Import	11	4. Diagnosis or Reason for	Use (Indication)		es No Doesn't
Required Interv	ention to Prevent Permanent Imp	pairment/Damage (I	Devices)	**	= +=)/	8. Event	Reappeared After oduction?
3. Date of Event (mm/	11.11.11.11	e of this Report (mi	m/dd/yyyy)	*1	#1 Tyes TNo Doesn't		
	08	3/01/2016		#2			es Live Li Apply
A COLUMN TO SERVICE AND ADDRESS OF THE PARTY	oblem or Product Use Error to report an adverse	o liberat crea		6. Lot #	7. Expiration Date	#2 Y	es No Doesn't
	wout Treatment. She			#1	#1	9. NDC #	or Unique ID
	the past without p			#2	#2		
	n and was given trea or three days. The			E. SUSPECT MEDIC	AL DEVICE		
	eft on the straighte			1. Brand Name			
	er washed her hair			2. Common Device Name			
	e missing and that l red on legs. She			z. Common Device Name			
	which to cut off be			3. Manufacturer Name, City	and State		
	months the caller ; after consulting with						
her it was sa	fe she received another	ther Brazili	an Blowout.	4. Model #	Lot#		5. Operator of Device
	returned the first			9. Model #	Lot		
another Brazilian Blowout. Almost immediately lesions appeared on both arms. Again she had extreme hair breakage. She says since then she had thick mucus in her nostrils. Caller says that she has anxiety about her appearance now. She says that prior to Brazilian Blowout in April she signed a Walver releasing salon			Catalog #	Expiration Date (mm/dd/yyyy) Lay User/Pat			
			Serial #	Other#		Other:	
from responsi	bility. She said eves it should be p	thinks produ	ct is not	6. If Implanted, Give Date (n	nm/dd/yyyy) 7. If Exp	planted, Giv	re Date (mm/dd/yyyy)
				8. Is this a Single-use Device Yes No	e that was Reprocessed	and Reused	d on a Patient?
				9. If Yes to Item No. 8, Enter	Name and Address of R	eprocessor	
				A 2 1 2 1 2 2 2 10 1 2 2 2			
6. Relevant Tests/Lab	poratory Data, Including Dates						
				F. OTHER (CONCOMITANT) MEDICAL PRODUCTS			
				Product names and therapy	y dates (exclude treatment	of event)	
7. Other Relevant His	tory, Including Preexisting Me	edical Conditions /	a allemies				
race, pregnancy, sm	noking and alcohol use, liver/kidn	ney problems, etc.)	.g., unergree,	G. REPORTER (See	confidentiality sec	tion on b	ack)
				1. Name and Address			
				(b) (6)			
				Marie and the second			
				Phone # (b) (6)	E-mail		
C DDODUOT	VAIL ADULTY			(b) (6) 2. Health Professional? 3.	(b) (6) Occupation		. Also Reported to:
C. PRODUCT A	VAILABILITY Evaluation? (Do not send prod	had to ETIAL		Yes No	TO THE PERSON NAMED IN COLUMN TWO IS NOT THE PERSON NAMED IN COLUMN TWO IS		Manufacturer
roduct Available for	Evaluation ! (Do not send prod	uci to PDA)			L. Park B. J.		User Facility
Yes No	Returned to Manufactu		n/dd/yyyy)	If you do NOT want your to the manufacturer, place			Distributor/Importer