U.S. Department of Health and Human Services

Internet Consumer Report 875M

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

For VOLUNTARY reporting of adverse events, product problems and product use errors 1/2

FDA USE ONLY
Triage unit sequence # 5416681

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	74 Years (b) (6)	☑ Female ☐ Male	200 lb 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**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/09/2014	04/11/2014

5. **Describe Event, Problem or Product Use Error**

On Wednesday April 9th I washed my haid with L'oreal Everstrong shampoo. Then used Suave Keratin infusion conditioner (new to me). Some of the conditioner ran down back of head and around my neck to the front. I leave conditioner on for 1-2 minutes while I do the body wash, heel scrub stuff. Then I rinsed. Got out of shower and dried, I went to the mirror to comb hair and I noticed that my face was very red and I had several red marks around my throat (I took a picture the next day). My back was itchy and when I looked into the mirror my back had a rash between my shoulder blades and down. I ...

6. **Relevant Tests/Laboratory Data, Including Dates**

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

Race:White

Medical Conditions:

Allergies:

Important Information:

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Keratin Infusion
Strength:
Manufacturer: Suave

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 04/09/2014 –
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 to condition hair
#2

6. Lot #	7. Expiration Date
#1 02254J036	#1
#2	#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** CTU

3. **Manufacturer Name, City and State** APR 14 2014

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	**Other #**	

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**

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**
Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b) (6) ZIP: (b) (6)

Phone #	E-mail
9285335079	azrose40@q.com

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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

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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.

U.S. Department of Health and Human Services

Internet Consumer Report 875172

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

For VOLUNTARY reporting of adverse events, product problems and product use errors 112

FDA USE ONLY
Triage unit sequence # 547413

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6)	0	☐ Female ☐ Male	____ lb or ____ kg
In confidence			

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**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/10/2013	04/18/2014

5. **Describe Event, Problem or Product Use Error**

In 2013 summer I was going to visit my country and before leaving I did keratin hair treatment with a well known saloon called beauty indulgence in sugar land, tx and before doing keratin treatment I went to see dermatologist first just to ask him that is it safe to do or not since I was having some dry skin too Doctor prescribed me one tube and said you can go ahead and do the treatment The night mare started after the month if treaement my forehead discolor and after three months when I came back to USA I see the dermatologist and he gave me triluma after like few days I was looking at me ...

6. **Relevant Tests/Laboratory Data, Including Dates**

Skin biopsy on March

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

Race:--

Medical Conditions:

Allergies:

Important Information:

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Keratin
Strength: Copalla
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 Prednisone	Once daily	Taken by mouth
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 Lichen planiplaruis
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

GTU
APR 21 2014

2. **Common Device Name**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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**

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**
Name: (b) (6)
Address: (b) (6)
City: Sugar land State: TX ZIP: 77479

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.

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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

May 02, 2014

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

This is a copy of your Report to the U.S. Consumer Product Safety Commission submitted on 4/30/2014

Incident Details

Document Number:	I1440557A
Report Number:	20140430-43443-2147444968
Report Submitted Date:	4/30/2014
Who You Are:	Consumer
Incident Description:	I have been using suave products exclusively for about 10 years and have never had something 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 Location:	Home/Apartment/Condominium - (b) (6) United States This is my home address

Victim Details

First Name	(b) (6)
Last Name:	(b) (6)
Injury Information:	Incident, No Injury
Victim is of Hispanic/Latino origin?	No
Race:	White
Other Race/Ethnicity:	
My Relationship to Victim:	Self
Gender:	Female
Age when	34 Years

CAERS 05/02/2014

incident occurred:	
Address:	(b) (6) , United States
E-mail:	(b) (6)
Phone Number:	(b) (6)

Product Details

Product Description:	The first product I used was Suave "keratin infusion heat defense leave in conditioner" A few weeks later I bought the matching shampoo and conditioner "natural infusion with awapuhi, ginger, and honeysuckle" listed as anti-breakage shampoo and conditioner.
Product Category:	Shampoo and Conditioner
Product Type:	
Brand Name:	Suave
Manufacturer / Importer / Private Labeler Name:	Unilever
Model Name or Number:	83223367, 83223359, 83176479
Serial Number:	01134JU36, 01044JU36
Date Manufactured:	
Manufacturer Date Code:	
Manufacturer Address:	Not specified
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 product in my possession.	Yes
The product was damaged before the incident.	N/A
The product was modified before the incident.	N/A
Have you contacted the manufacturer?	Yes

If not, do you plan to contact them?	N/A
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 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?	No, do not include my Report on SaferProducts.gov.
May we release your name and contact information to the product manufacturer / importer / private labeler identified in your Report?	Yes, you may release my name and contact information to the product manufacturer /importer / private labeler.
I certify that I 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.	Yes

OMB Control Number 3041-0146

May 21, 2014

Unilever Home & Personal Care USA (Division
of Conopco, 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.

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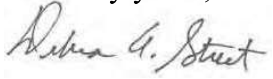
To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 176203.

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

Sincerely yours,



Debra Street
Chief
Emergency Response and Surveillance Branch
Center for Food Safety
and Applied Nutrition

Enclosure

CFSAN

1/2

U.S. Department of Health and Human Services

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

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

FDA USE ONLY
Triage unit sequence # 549390

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	30 Years (b) (6)	☑ Female ☐ Male	140 lb 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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/29/2014	05/06/2014

5. Describe Event, Problem or Product Use Error

Got a Brazilian blowout and was told formaldehyde only affects the hairdresser. I have now been sick for a week after. I'm nauseous all the time, have constant headaches, fatigue after 3 hours of movement and have no appetite at all. I feel miserable for a person that is so healthy. I don't smoke or drink at all. I eat organic and gluten free most of the time. I workout and go to yoga regularly.

6. Relevant Tests/Laboratory Data, Including Dates

Going to the dr on Thursday.

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

Race:White

For additional information see B7 below.

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Formaldehyde
Strength: Brazilian blowout
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 04/29/2014 –
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Straighten hair
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: CTU

2. Common Device Name: MAY – 7 2014

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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
Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b) (6) ZIP: (b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

549390

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

U.S. Department of Health and Human Services

Internet Consumer Report

CFSAN

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

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

1/2

FDA USE ONLY

Triage unit sequence #: 549495

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6)	27 Years (b) (6)	☑ Female ☐ Male	153 lb or ____ kg

In confidence

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**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/25/2014	05/07/2014

5. **Describe Event, Problem or Product Use Error**

Used a keratin hair smoothing treatment 2weeks ago and have continued to have blisters appear on my neck and around my hairline.

6. **Relevant Tests/Laboratory Data, Including Dates**

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

Race:Black/African American

For additional information see B7 below.

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: keratin treatments
Strength: smooth and shine keratin power
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	---	---
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*

#1 04/25/2014 –

#2

4. **Diagnosis or Reason for Use** *(Indication)*

#1 Straighten hair

#2

5. **Event Abated After Use Stopped or Dose Reduced?**

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

CTU

MAY – 8 2014

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:
Serial #	**Other #**	

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**

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**

Name: (b) (6)
Address: (b) (6)

City: Kingsport State: TN ZIP: 37664

Phone #	E-mail
	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.

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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: Hydrocodone

Important Information: Smoker

RX Meds: Phentermine 37mg

OTC Meds: B12

U.S. Department of Health and Human Services

Internet Consumer Report 37512

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

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

113

FDA USE ONLY

Triage unit sequence # 550620

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	43 Years	☑ Female ☐ Male	165 lb 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

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

☐ Death: ____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
05/16/2014	05/18/2014

5. Describe Event, Problem or Product Use Error

I had "keratin conditioning" treatment on Friday afternoon. The brand of keratin was GK / Global Keratin. I do not know of a specific formulation. My hair was washed and then the keratin applied to my towel dried hair. The cosmetologist used a bowl and brush to apply the solution. When the application was complete, I sat for about 5 minutes, then she used a blow drier to dry my hair. She then used a hot flat iron on my hair. During the hot iron portion of the treatment, I felt my scalp tingling but it did not seem significant at the time. About 24 hours after the treatment, my scalp began ...

6. Relevant Tests/Laboratory Data, Including Dates

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

Race: White

For additional information see B7 below.

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Global Keratin
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*

#1
#2

4. Diagnosis or Reason for Use *(Indication)*

#1 Hair conditioning treatment
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

MAY 19 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

Name (b) (6)
Address: (b) (6)
City: (b) (6) State (b) (6) ZIP: (b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.

000001

5506020

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)

5506020

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

June 03, 2014

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

U.S. Department of Health and Human Services

Internet Consumer Report 83SAX

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

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

18

FDA USE ONLY

Triage unit sequence # 552932

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	61 Years (b) (6)	☑ Female ☐ Male	180 lb 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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
05/16/2014	06/04/2014

5. Describe Event, Problem or Product Use Error

I am a 62 year old white female who was born with 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 fall out. I get my hair cut every 5 weeks and my hair dresser is very alarmed at the noticeable hair loss I have experienced.

6. Relevant Tests/Laboratory Data, Including Dates

Recent blood lab ...

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

Race: White

For additional information see B7 below.

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Keratin Smooth 7-Day Smooth Syst
Strength:
Manufacturer: Tresemme

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 about 1 month	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*

#1 Temporarily straighten curly, frizzy hair.

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

JUN - 5 2014

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	

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

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

Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b) (6) ZIP: (b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer
		☐ User Facility
		☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

552932

B.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.

552932

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: High blood pressure

Allergies: None

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/Chrondroitin (Advanced Formula), Biotin (10,000 mcg)

June 25, 2014

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		

Complainant Identification			
Name	(b) (6)	**Work Phone**	
Address	(b) (6)	**Home Phone**	(b) (6)
		Source POC Name	
City	(b) (6)	**Source Phone**	
State			
Zip	(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
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

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.

Product and Labeling

Brand Name	Coppola		
Product Name	Keratin Complex Smoothing Therapy		
FDA Product Code	53ED03	**Qty/Unit**	
UPC Code		**Package**	
Exp/Use By Date		**Lot/Serial**	
Product Used?	No	**Purchase Date**	
Date Used?		**Amount Consumed/Used**	
Amount Remained		**Date Discontinued**	
Country of Origin		**Imported Product?**	No
Retailer Name		**Label Remarks**	

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**	

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]

June 24, 2014

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.

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 # 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

U.S. Department of Health and Human Services

Internet CFSAN Consumer Report

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

1/2

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 # 554723

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	25 Years (b) (6)	☑ Female ☐ Male	125 lb 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**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/18/2014	06/22/2014

5. **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 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 ...

6. **Relevant Tests/Laboratory Data, Including Dates**

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

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Brazilian Blowout
Strength: Brazilian Blowout
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	—	—
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

CTU

3. **Manufacturer Name, City and State**

JUN 23 2014

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	**Other #**	

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**

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**
Name: (b) (6)
Address: (b) (6)
City: Wyomissing State: PA ZIP: 19610

Phone #	E-mail
	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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

554723

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		

Complainant Identification			
Name	(b) (6)	**Work Phone**	
Address	(b) (6)	**Home Phone**	(b) (6)
		Source POC Name	
City	(b) (6)	**Source Phone**	
State	(b) (6)		
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

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

Initial Evaluation / Initial Disposition

Initial Evaluation	FDA Action Indicated	**Initial Disposition**	Referred to Other FDA District
Disposition Date	07/09/2014		

Remarks
Brazilian Blowout CEO Mark Brady (877-779-7706 x2150) confirmed manufacturer. Mr. Brady advised 2-3 similar complaints received over last 6 years. Complainant gives permission to release personal information to company.

Problem Keyword	Problem Keyword Details
Other	thinning hair, losing hair

Cosmetic

Cosmetic ID #(b) (6)

DOB	(b) (6)	**Age**	58
Gender	Female	**Race**	Question Not Asked
Application Place	Salon/SPA	**Reason for Use**	Hair Preparations (Non-Coloring)
Application Site	Hair	**Other Products?**	Yes

Directions
Three pumps is enough is enough for one treatment

Directions Followed?	Yes	**Product Duration**	
Frequency of Use	Other	**Reaction Site**	Scalp
Product Use in Off-Label Manner?	No	**Off-Label Manner Desc**	
Warning Statement on Label?	Yes	**Warning Statements?** This product contains methylene glyco. When heated, this ingredient releases formaldehyde gas. Use in well-vetinlated area and only as directed.	
Preexisting Conditions?	No	**Treatment**	Physician
Current Status	Unchanged		
Medical Diagnosis		**Medical Treatment** Dermatologist advised taking 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]

U.S. Department of Health and Human Services

Internet Consumer Report 03SAF

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

For VOLUNTARY reporting of adverse events, product problems and product use errors 1/3

FDA USE ONLY
Triage unit sequence # 5572608

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	39 Years (b) (6)	☑ Female ☐ Male	115 lb 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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
07/14/2014	07/14/2014

5. Describe Event, Problem or Product Use Error

I Am a licensed cosmetologist, I have been practicing for approximately 22 years. In the last five years a product called Brazilian blowout, and now known as keratin treatments have become popular. Since my first exposure to the smoke being burned In the air, I noticed it made me sick. I chose to never do them, however other stylist do. Now, five years later....I am confident after last weeks exposure that this treatment is making me very sick. This is my second chemicals burn in my throat after being exposed to the chemicals by just being at work while another stylist was doing one. Not it ...

6. Relevant Tests/Laboratory Data, Including Dates

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

Race:White

For additional information see B7 below.

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Keratin treatment
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 To straighten and smoothe the hair.
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name CTU

3. Manufacturer Name, City and State JUL 15 2014

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	

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

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
Name: (b) (6)
Address:
City: State: -- ZIP:

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.5. **Describe Event or Problem** *(continued)*

5572608

... 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

5572608

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

U.S. Department of Health and Human Services

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

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

FDA USE ONLY	
Triage unit sequence #	561714

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	39 Years (b) (6)	☑ Female ☐ Male	____ lb 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**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/20/2014	08/21/2014

5. **Describe Event, Problem or Product Use Error**
See page 2 for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**
See page 3 for complete text.

7. **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.

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Brazilian Blowout
Strength:
Manufacturer: Brazilian Blowout

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. **Dates of Use** *(if unknown, give duration) from/to (or best estimate)*
#1 08/20/2014 - 08/20/2014
#2

4. **Diagnosis or Reason for Use** *(indication)*
#1 Hair straightening
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

CTU
AUG 22 2014

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:
Serial #	**Other #**	

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**

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**
Name: (b) (6)
Address:
City: State: -- ZIP:

Phone #	E-mail
	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer
		☐ User Facility
		☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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

5C01714

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

5 61714

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

August 26, 2014

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

Enclosure

U.S. Department of Health and Human Services

Internet Consumer Report 875N

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

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

1/3

FDA USE ONLY

Triage unit sequence # BC01940

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6)	51 Years (b) (6)	☑ Female ☐ Male	145 lb or ____ kg

in confidence

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**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/22/2014	08/23/2014

5. **Describe Event, Problem or Product Use Error**
See page 2 for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **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.

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Brazilian Blowout (Keratin)
Strength: not known by this consumer
Manufacturer: Brazilian Blowout

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 08/22/2014 –
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 To calm curly, frizzy hair.
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Expiration Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

CTU

2. **Common Device Name**

AUG 25 2014

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:
Serial #	**Other #**	

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**

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**
Name (b) (6)
Address (b) (6)
City (b) (6) State (b) (6) ZIP (b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.

000001

561940

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

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

August 26, 2014

To Whom It May Concern:

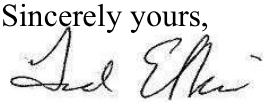
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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 # 178843.

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

U.S. Department of Health and Human Services

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. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence # 178972

2153

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
In confidence	(b) (6)	☑ Female ☐ Male	136 lb 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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   ☐ Death: _____ *(mm/dd/yyyy)*
   ☐ Life-threatening
   ☐ Hospitalization - initial or prolonged
   ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   ☐ Disability or Permanent Damage
   ☐ Congenital Anomaly/Birth Defect
   ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
8-30-2014	09/02/2014

5. Describe Event, Problem or Product Use Error

Consumer went to hair Salon to have have shampoo and dry, and was offered for free a Brazilian Blow Out. She later learn from another hair stylist that you cannot at the last min have a Brazillian Blow Out, the reason being: for one week you need to not put any grease or any other product in the scalp. Consumer agreed and the hair style done to her head. Later that night consumer had hair loss and burning sensation, itchy, tingling sensation, irritation, dryness. Consumer complains that carbon bioxide, formadahyde ingredients are the cause for the hair loss. Consumer approach the person who did her hair and was not given a clear answer. Yehia Company 1455 East 53rd Chicago IL

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Brazilian Blow Out
   #2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 8-30-2014
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☑ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
   #1
   #2

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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
   (b) (6)

Phone #	E-mail
(b) (6)	

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

September 15, 2014

Yehia Company
1455 East 53rd
Chicago, Illinois 60018

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 # 178972.

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

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

Complaint / Injury			
Complaint Description		**Adverse Event Result**	None
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 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.

Product and Labeling			
Brand Name	Brazilian Blowout		
Product Name	Acai Professional 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**	

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 / Initial Disposition

Initial Evaluation	FDA Action Indicated	**Initial Disposition**	Referred to Other FDA District
Disposition Date	06/03/2014		

Remarks
No additional product information 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]

October 09, 2014

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.

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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

Enclosure

U.S. Department of Health and Human Services

Internet Consumer Report 6754

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

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

14

FDA USE ONLY
Triage unit sequence # 5 of 025

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	29 Years (b) (6)	☑ Female ☐ Male	137 lb 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**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/15/2014	09/10/2014

5. **Describe Event, Problem or Product Use Error**
See page 2 for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**
See page 3 for complete text.

7. **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.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
#1 Name: Brazilian Blowout
Strength: Brazilian Blowout
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	---	--
#2		

3. ***Dates of Use*** *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. ***Event Abated After Use*** **Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** CTU

3. **Manufacturer Name, City and State** SEP 11 2014

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	**Other #**	

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**

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**
Name: Florence Millon
Address:

City: State: -- ZIP

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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

5604025

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.

564025

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

Biopsy of neck lesion: eczematous dermatitis

5 6 4025

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

U.S. Department of Health and Human Services

CFSAN

Internet Consumer Report

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

1/2

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 # 578527

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	____ lb 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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
01/07/2015	01/08/2015

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 1 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Keratin treatment Rejuvenol
Strength: ?wasnt told
Manufacturer: Rejuvenol

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. Diagnosis or Reason for Use *(indication)*
#1 Straightening the hair
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU

2. Common Device Name

JAN - 9 2015

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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
Name (b) (6)
Address (b) (6)
City: (b) (6) State: (b) (6) ZIP: (b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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

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

February 05, 2015

Rejuvenol
415 Bayview Ave
Amityville, New York 11701

To Whom It May Concern:

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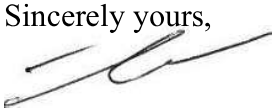
We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

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 # 181880.

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

Sincerely yours,



Lyle Canida, Pharm.D., M.S.
LCDR, U.S. Public Health Service
Branch Chief, Signals Management Branch
Division of Public Health Informatics & Analytics
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure

U.S. Department of Health and Human Services

CFSAN
Internet Consumer Report

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

1/4

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 #	579258

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	148 lb 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**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
01/08/2015	01/14/2015

5. **Describe Event, Problem or Product Use Error**
See page 2 for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**
See page 3 for complete text.

7. **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.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
#1 Name: Brazilian Blowout
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 01/08/2015 –
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1 This product was applied by a professional stylist at salon
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

CTU

3. **Manufacturer Name, City and State**

JAN 15 2015

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	**Other #**	

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**

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**
Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b) (6) ZIP: (b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer
		☐ User Facility
		☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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

579258

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

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

579258

No tests taken at this point

5792258

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)

RX Meds: None

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

January 29, 2015

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.

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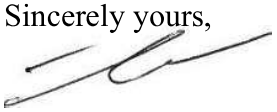
If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,



Lyle Canida, Pharm.D., M.S.
LCDR, U.S. Public Health Service
Branch Chief, Signals Management Branch
Division of Public Health Informatics & Analytics
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure

U.S. Department of Health and Human Services

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

CFSAN

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

1 of 5

FDA USE ONLY
Triage unit sequence # 583819

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	162 lb or ____ kg

2. Dose or Amount / Frequency / Route

#1

#2

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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 straighten hair
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Expiration Date
#1
#2

9. NDC # or Unique ID

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
02/11/2015	02/13/2015

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. 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.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Original Keratin
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU

FEB 18 2015

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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
Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b)(6) ZIP: (b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.

000001

1 of 5

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.

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

583819

Race:White
Medical Conditions: low thyroid

Allergies: none

Important Information: none

RX Meds: 75 mg levothyroxine daily

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

March 09, 2015

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

To Whom It May Concern:

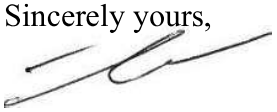
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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 # 183072.

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

Sincerely yours,



Lyle Canida, Pharm.D., M.S.
LCDR, U.S. Public Health Service
Branch Chief, Signals Management Branch
Division of Public Health Informatics & Analytics
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure

U.S. Department of Health and Human Services

Internet Consumer Report CFSAN

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

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

1/2

FDA USE ONLY

Triage unit sequence # 590205

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	36 Years (b) (6)	☑ Female ☐ Male	215 lb 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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/29/2015	03/31/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

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

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Keratin Color
Strength: Cashmere brown
Manufacturer: schwarzkopf

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 03/29/2015 - 03/29/2015
#2

4. Diagnosis or Reason for Use *(indication)*
#1 Dying my hair
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

APR - 1 2015

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

See additional page(s) for complete text.

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: (b) (6)
Address (b) (6)
City: Tampa State: FL ZIP: 33629

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.

000001

596205

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

June 25, 2015

Schwarzkopf

,

To Whom It May Concern:

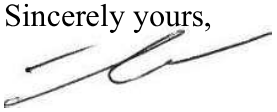
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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

Enclosure

CFSAN

U.S. Department of Health and Human Services

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

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

FDA USE ONLY
Triage unit sequence #
594169

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	59 Years	☑ Female ☐ Male	____ lb 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**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/21/2015	04/24/2015

5. **Describe Event, Problem or Product Use Error**

See additional page(s) for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**

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

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Brazilian Blowout
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	—	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 04/21/2015 –	#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. **Diagnosis or Reason for Use** *(indication)*
#1 Stylist indicated it smooths hair
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

CTU
APR 27 2015

2. **Common Device Name**

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:
Serial #	**Other #**	

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**

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**
Name: (b) (6)
Address:
City: 7 State: ZIP:

Phone #	E-mail
1	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.

000001

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, race, 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)*

U.S. Department of Health and Human Services

Internet Consumer Report

CFSAN

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

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

1/2

FDA USE ONLY

Triage unit sequence #

602433

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	44 Years (b) (6)	☑ Female ☐ Male	___ lb or 78 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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   ☐ Death: ___ *(mm/dd/yyyy)*
   ☐ Life-threatening
   ☐ Hospitalization - initial or prolonged
   ☑ Disability or Permanent Damage
   ☐ Congenital Anomaly/Birth Defect
   ☑ Other Serious (Important Medical Events)
   ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/16/2015	06/23/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

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

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ___ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Global Keratin
Strength: NA
Manufacturer: GK Hair

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	—	..
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 06/16/2015 – 06/16/2015	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 Hair treatment
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU

2. Common Device Name

JUN 24 2015

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

See additional page(s) for complete text.

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b) (6) ZIP (b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.

000001

602433

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

October 05, 2015

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

To Whom It May Concern:

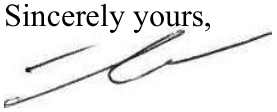
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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

Enclosure

U.S. Department of Health and Human Services

Internet Consumer Report CFSAN

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

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

FDA USE ONLY

Triage unit sequence #

607597

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6)	40 Years	☑ Female ☐ Male	135 lb or ____ kg

In confidence

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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
07/08/2015	07/27/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

See additional page(s) for complete text.

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

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Brazilian Blowout
Strength
Manufacturer: Malibu California 877-779-7706

#2 Name:
Strength
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 apply lightly to hair	every 3 months	Applied to a surface, usually the skin
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 07/08/2015 –	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 hair straightening and reduce frizz product
#2

6. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 120015F2	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

JUL 28 2015

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

See additional page(s) for complete text.

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: (b) (6)
Address: (b) (6)
City: Fargo State: ND ZIP: 58102

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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.

000001

607597

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 Mall 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 slow 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 reaction 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 body to have a reaction. Brazilian Blowout should be banned in the US like it is in other ROW countries.

B.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)** *(continued)*

RX Meds: none

OTC Meds: none

October 30, 2015

Primp Salon
4325 Glenwood Ave.
Raleigh, North Carolina 27612

To Whom It May Concern:

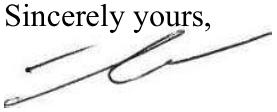
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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.

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 # 188289.

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

Sincerely yours,



Lyle Canida, Pharm.D., M.S.
LCDR, U.S. Public Health Service
Branch Chief, Signals Management Branch
Division of Public Health Informatics & Analytics
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Page ____ of ____

1903711

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

FDA USE ONLY

Triage unit sequence #

071538

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lb 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

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

☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	10/06/2015

5. Describe Event, Problem or Product Use Error

Reaction to product. Product is distributed by GH hair in FL

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Keratin Hair Treatment

#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*

#1

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

(b) (6)

Phone #	E-mail
831-524-2855	

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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

February 04, 2016

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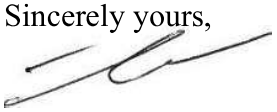
If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,



Lyle Canida, Pharm.D., M.S.
LCDR, U.S. Public Health Service
Branch Chief, Signals Management Branch
Division of Public Health Informatics & Analytics
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure

February 04, 2016

BRAZILIAN BLOWOUT
28001 DOROTHY DR
AGOURA HILLS, California 91301

To Whom It May Concern:

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

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

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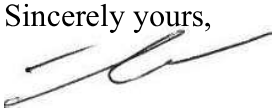
If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,



Lyle Canida, Pharm.D., M.S.
LCDR, U.S. Public Health Service
Branch Chief, Signals Management Branch
Division of Public Health Informatics & Analytics
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure

U.S. Department of Health and Human Services

Internet Consumer Report

Form Approved: OMB 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 #	654302
FDA Rec. Date	

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6) In Confidence

2. **Age** ☑ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s): 28
or Date of Birth *(e.g., 08 Feb 1925)*

3. **Sex** ☑ Female ☐ Male

4. **Weight** 140 ☑ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**
☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy)* _____
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)*: 11-Apr-2016

4. **Date of this Report** *(dd-mmm-yyyy)*: 04-May-2016

5. **Describe Event, Problem or Product Use Error**
See additional page(s) for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

1. **Name, Manufacturer/Compounder, Strength** *(from product label)*

#1 - Name and Strength	#1 - NDC # or Unique ID
Keratin cure chocolate max vl	
#1 - Manufacturer/Compounder	**#1- Lot #**
Keratin Cure	
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

3.	Dose or Amount	Frequency	Route
#1		--	--
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 11-Apr-2016 –
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 straightens hair
#2

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☐ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 #2

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

CTO MAY – 5 2016

2. **Common Device Name** 2b. **Procode**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date *(dd-mmm-yyyy)*	☐ Lay User/Patient
		☐ Other
Serial #	Unique Identifier (UDI) #	

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* 7. **If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(Exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
Last Name: (b) (6) First Name: (b) (6)
Address:
City: State/Province/Region:
Country: ZIP/Postal Code:
Phone #: E-mail:

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer/ Compounder
		☐ User Facility
		☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☑

PLEASE TYPE OR USE BLACK INK

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

B.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)*

U.S. Department of Health and Human Services

Internet Consumer Report

Form Approved: OMB 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 #	654302
FDA Rec. Date	

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6) In Confidence

2. **Age** ☑ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s): 28
or Date of Birth *(e.g., 08 Feb 1925)*

3. **Sex**: ☑ Female ☐ Male

4. **Weight**: 140 ☑ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*: ☐ Hispanic/Latino ☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*: ☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**

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

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*

☐ Death *Include date (dd-mmm-yyyy)* _____
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)*	4. **Date of this Report** *(dd-mmm-yyyy)*
11-Apr-2016	04-May-2016

5. **Describe Event, Problem or Product Use Error**
See additional page(s) for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

1. **Name, Manufacturer/Compounder, Strength** *(from product label)*

#1 - Name and Strength	#1 - NDC # or Unique ID
Keratin cure chocolate max vl	
#1 - Manufacturer/Compounder	**#1- Lot #**
Keratin Cure	
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

3.	Dose or Amount	Frequency	Route
#1		--	--
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 11-Apr-2016 –
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 straightens hair
#2

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☐ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 #2

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

CTU
MAY – 5 2016

2. **Common Device Name** | 2b. **Procode**

3. **Manufacturer Name, City and State**

4. **Model #**	**Lot #**	5. **Operator of Device**
Catalog #	**Expiration Date** *(dd-mmm-yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other
Serial #	**Unique Identifier (UDI) #**	

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* | 7. **If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(Exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**

Last Name: (b) (6) | First Name: (b) (6)
Address:
City: | State/Province/Region:
Country: | ZIP/Postal Code:
Phone #: | E-mail:

2. **Health Professional?**	3. **Occupation**	4. **Also Reported to:**
☐ Yes ☐ No		☑ Manufacturer/ Compounder
5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☑		☐ User Facility ☐ Distributor/Importer

PLEASE TYPE OR USE BLACK INK

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

B.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)*

beauty COSMETICA Professional dba KÉRATIN CURE MIAMI
RE-INVENT YOURSELF!

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

BEAUTY COSMETICA CORPORATION
CORPORATE SEAL 2009
FLORIDA
KERATIN CURE

'16 JL 25

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

June 29, 2016

BEAUTY COSMETICA
3406 NW 151 Terrace
Miami Gardens, Florida 33054

To Whom It May Concern:

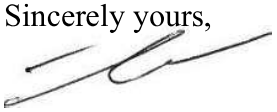
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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.

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 # 196079.

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

Sincerely yours,



Lyle Canida, Pharm.D., M.S.
LCDR, U.S. Public Health Service
Branch Chief, Signals Management Branch
Division of Public Health Informatics & Analytics
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure

Internet Consumer Report

CFSAN

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 09/30/2016
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 #	657542
FDA Rec. Date	

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In Confidence

2. Age: ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)
or Date of Birth (e.g., 08 Feb 1925): (b) (6)

3. Sex: ☑ Female ☐ Male

4. Weight: 128 ☑ lb ☐ kg

5.a. Ethnicity (Check single best answer)
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. Race (Check all that apply)
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☑ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply
☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply)
☐ Death Include date (dd-mmm-yyyy): _____
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects
☑ Other Serious (Important Medical Events) migrane, burned air passage
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy): 18-May-2016

4. Date of this Report (dd-mmm-yyyy): 19-May-2016

5. Describe Event, Problem or Product Use Error
See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ (dd-mmm-yyyy)

D. SUSPECT PRODUCTS

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

#1 - Name and Strength	#1 - NDC # or Unique ID
Brazilian Blowout	
#1 - Manufacturer/Compounder	#1- Lot #
EBG	
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2- Lot #

	3. Dose or Amount	Frequency	Route
#1		—	topical
#2			

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)
#1 01-May-2012 - 18-May-2016
#2

5. Diagnosis or Reason for Use (indication)
#1 in salon smoothing treatment
#2

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☑ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. Expiration Date (dd-mmm-yyyy) #1 #2

9. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

CTU
MAY 20 2016

4. Model # | Lot #

Catalog # | Expiration Date (dd-mmm-yyyy)

Serial # | Unique Identifier (UDI) #

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

6. If Implanted, Give Date (dd-mmm-yyyy) | 7. If Explanted, Give Date (dd-mmm-yyyy)

8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
Last Name: (b) (6) First Name: (b) (6)
Address: 405 south 2nd street
City: (b) (6) State/Province/Region: (b) (6)
Country: US ZIP/Postal Code: (b) (6)
Phone #: (b) (6) E-mail: (b) (6)

2. Health Professional? ☐ Yes ☐ No

3. Occupation

4. Also Reported to:
☐ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK

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.

657542

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

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

CFSAN

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 09/30/2016
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

(2)

FDA USE ONLY

Triage unit sequence # 657542

FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)

In Confidence

2. Age ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth (e.g., 08 Feb 1925) (b) (6)

3. Sex ☑ Female ☐ Male

4. Weight 128 ☑ lb ☐ kg

5.a. Ethnicity (Check single best answer)
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. Race (Check all that apply)
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☑ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply
☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply)
☐ Death Include date (dd-mmm-yyyy): _____
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects
☑ Other Serious (Important Medical Events) migrane, burned air passage
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy): 18-May-2016

4. Date of this Report (dd-mmm-yyyy): 19-May-2016

5. Describe Event, Problem or Product Use Error
See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ (dd-mmm-yyyy)

D. SUSPECT PRODUCTS

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

#1 - Name and Strength	#1 - NDC # or Unique ID
Brazilian Blowout (1)	
#1 - Manufacturer/Compounder: EBG	#1- Lot #
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2- Lot #

3.	Dose or Amount	Frequency	Route
#1		—	topical
#2			

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)
#1 01-May-2012 - 18-May-2016
#2

5. Diagnosis or Reason for Use (indication)
#1 in salon smoothing treatment
#2

6. Is the Product Compounded?
#1 ☐ Yes ☑ No
#2 ☐ Yes ☐ No

7. Is the Product Over-the-Counter?
#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No

9. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

8. Expiration Date (dd-mmm-yyyy) #1 #2

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

CTU

MAY 20 2016

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device
☐ Health Professional
☐ Lay User/Patient
☐ Other:

Catalog # | Expiration Date (dd-mmm-yyyy)

Serial # | Unique Identifier (UDI) #

6. If Implanted, Give Date (dd-mmm-yyyy) | 7. If Explanted, Give Date (dd-mmm-yyyy)

8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
Last Name (b) (6) First Name (b) (6)
Address: 405 south 2nd street
City (b) (6) State/Province/Region (b) (6)
Country: US ZIP/Postal Code
Phone #: (b) (6) E-mail (b) (6)

2. Health Professional? ☐ Yes ☐ No

3. Occupation

4. Also Reported to:
☐ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK

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.

657542

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

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)*

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Internet Consumer Report

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

CFSAN

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

FDA USE ONLY

Triage unit sequence # 659472

FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6)

In Confidence

2. **Age** 30 ☑ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth *(e.g., 08 Feb 1925)*

3. **Sex** ☑ Female ☐ Male

4. **Weight** 115 ☑ lb ☐ kg

5.a **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☑ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**
☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* _____
☐ Life-threatening ☑ Disability or Permanent Damage
☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)* 16-Apr-2016

4. **Date of this Report** *(dd-mmm-yyyy)* 28-May-2016

5. **Describe Event, Problem or Product Use Error**
See additional page(s) for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**
See additional page(s) for complete text.

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

1. **Name, Manufacturer/Compounder, Strength** *(from product label)*

#1 - Name and Strength	#1 - NDC # or Unique ID
Brazilian Blowout Acai Professi	
#1 - Manufacturer/Compounder	**#1- Lot #**
Brazilian Blowout	
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

	3. Dose or Amount	Frequency	Route
#1		--	Applied to a surface, usually the skin
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 16-Apr-2016 - 16-Apr-2016
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 Hair smoothing treatment
#2

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☑ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☑ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☑ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 #2

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** 2b. **Procode**

3. **Manufacturer Name, City and State**

CTU
MAY 31 2016

4. **Model #** **Lot #**

Catalog # **Expiration Date** *(dd-mmm-yyyy)*

Serial # **Unique Identifier (UDI) #**

6. **Operator of Device**
☐ Health Professional
☐ Lay User/Patient
☐ Other: _____

8. **If Implanted, Give Date** *(dd-mmm-yyyy)* 7. **If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(Exclude treatment of event)*
See additional page(s) for complete text.

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
Last Name: (b) (6) First Name: (b) (6)
Address:
City: State/Province/Region:
Country: ZIP/Postal Code:
Phone #: E-mail:

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:**
☐ Manufacturer/Compounder
☐ User Facility
☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (10/16) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

659472

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

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

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

CFSAN

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

FDA USE ONLY

Triage unit sequence # 659472

FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)

In Confidence

2. Age: 30 ☑ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth *(e.g., 08 Feb 1925)*

3. Sex: ☑ Female ☐ Male

4. Weight: 115 ☑ lb ☐ kg

5.a Ethnicity *(Check single best answer)*

☐ Hispanic/Latino

☑ Not Hispanic/Latino

5.b. Race *(Check all that apply)*

☐ Asian ☐ American Indian or Alaskan Native

☐ Black or African American ☑ White

☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply

☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*

☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event *(Check all that apply)*

☐ Death *Include date (dd-mmm-yyyy):* _____

☐ Life-threatening ☑ Disability or Permanent Damage

☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects

☐ Other Serious (Important Medical Events)

☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(dd-mmm-yyyy)*: 16-Apr-2016

4. Date of this Report *(dd-mmm-yyyy)*: 28-May-2016

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

See additional page(s) for complete text.

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

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength *(from product label)*

#1 - Name and Strength	#1 - NDC # or Unique ID
Brazilian Blowout Acai Professi	
#1 - Manufacturer/Compounder	**#1- Lot #**
Brazilian Blowout	
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

	3. Dose or Amount	Frequency	Route
#1		--	Applied to a surface, usually the skin
#2			

4. Dates of Use *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*

#1 16-Apr-2016 - 16-Apr-2016

#2

5. Diagnosis or Reason for Use *(indication)*

#1 Hair smoothing treatment

#2

9. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't apply

#2 ☐ Yes ☐ No ☐ Doesn't apply

10. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't apply

#2 ☐ Yes ☐ No ☐ Doesn't apply

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☑ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. Expiration Date *(dd-mmm-yyyy)* #1 #2

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

CTU MAY 31 2016

4. Model # | Lot #

Catalog # | Expiration Date *(dd-mmm-yyyy)*

Serial # | Unique Identifier (UDI) #

6. Operator of Device

☐ Health Professional

☐ Lay User/Patient

☐ Other: _____

8. If Implanted, Give Date *(dd-mmm-yyyy)* | 7. If Explanted, Give Date *(dd-mmm-yyyy)*

8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(Exclude treatment of event)*

See additional page(s) for complete text.

G. REPORTER *(See confidentiality section on back)*

1. Name and Address

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

Address:

City: | State/Province/Region:

Country: | ZIP/Postal Code:

Phone #: | E-mail:

2. Health Professional? ☐ Yes ☐ No

3. Occupation

4. Also Reported to:

☐ Manufacturer/ Compounder

☐ User Facility

☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK

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.

659472

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

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

June 27, 2016

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

To Whom It May Concern:

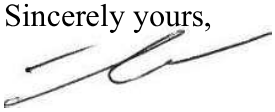
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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

Enclosure

U.S. Department of Health and Human Services

Internet Consumer Report

CFSAN

Form Approved: OMB 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 # 1616273

FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier	2. Age	3. Sex	4. Weight
(b) (6) In Confidence	☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s) or Date of Birth *(e.g., 08 Feb 1925)* (b) (6)	☑ Female ☐ Male	144 ☑ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
- ☐ Hispanic/Latino
- ☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
- ☐ Asian
- ☐ American Indian or Alaskan Native
- ☐ Black or African American
- ☑ White
- ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply
- ☑ Adverse Event
- ☐ Product Problem *(e.g., defects/malfunctions)*
- ☐ Product Use Error
- ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event *(Check all that apply)*
- ☐ Death *include date (dd-mmm-yyyy):* _____
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☑ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defects

3. Date of Event *(dd-mmm-yyyy)*	4. Date of this Report *(dd-mmm-yyyy)*
20-Jun-2016	04-Jul-2016

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

See additional page(s) for complete text.

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

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength *(from product label)*

#1 - Name and Strength	#1 - NDC # or Unique ID
Brazilian blowout acai anti frix, 12 350 ml	
#1 - Manufacturer/Compounder	**#1- Lot #**
GIB LLC	994715D
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

3.	Dose or Amount	Frequency	Route
#1	2 Ounce(s)	Once a day	Washed my hair with it
#2			

4. Dates of Use *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
- #1 16-Jun-2016 - 03-Jul-2016
- #2

5. Diagnosis or Reason for Use *(indication)*
- #1 Smoothing for hair
- #2

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☑ Yes ☐ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. Expiration Date *(dd-mmm-yyyy)* #1 _____ #2 _____

9. Event Abated After Use Stopped or Dose Reduced?
- #1 ☐ Yes ☑ No ☐ Doesn't apply
- #2 ☐ Yes ☐ No ☐ Doesn't apply

10. Event Reappeared After Reintroduction?
- #1 ☑ Yes ☐ No ☐ Doesn't apply
- #2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name | **2b. Procode** CTU

3. Manufacturer Name, City and State

JUL - 5 2016

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(dd-mmm-yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(dd-mmm-yyyy)* | **7. If Explanted, Give Date** *(dd-mmm-yyyy)*

8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(Exclude treatment of event)*

See additional page(s) for complete text.

G. REPORTER *(See confidentiality section on back)*

1. Name and Address

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

Address: (b) (6)

City: (b) (6) State/Province/Region:

Country: US ZIP/Postal Code: (b) (6)

Phone #: (b) (6) E-mail: (b) (6)

2. Health Professional? ☐ Yes ☐ No

3. Occupation

4. Also Reported to:
- ☐ Manufacturer/ Compounder
- ☐ User Facility
- ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☑

PLEASE TYPE OR USE BLACK INK

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

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 nasal 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.

B.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:

U.S. Department of Health and Human Services

Internet Consumer Report

CFSAN

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

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5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☑ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
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B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**
☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *include date (dd-mmm-yyyy):* _____
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

3. Date of Event *(dd-mmm-yyyy)*	4. Date of this Report *(dd-mmm-yyyy)*
20-Jun-2016	04-Jul-2016

5. **Describe Event, Problem or Product Use Error**
See additional page(s) for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**
See additional page(s) for complete text.

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

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

1. **Name, Manufacturer/Compounder, Strength** *(from product label)*

#1 - Name and Strength	#1 - NDC # or Unique ID
Brazilian blowout acai anti frizz, 12 350 ml	
#1 - Manufacturer/Compounder	**#1 - Lot #**
GIB LLC	994715D
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

3.	Dose or Amount	Frequency	Route
#1	2 Ounce(s)	Once a day	Washed my hair with it
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 16-Jun-2016 - 03-Jul-2016
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 Smoothing for hair
#2

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☑ Yes ☐ No	#1 ☑ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)* #1 #2

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☑ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☑ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** | 2b. **Procode** CTU

3. **Manufacturer Name, City and State**

JUL - 5 2016

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	**Expiration Date** *(dd-mmm-yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	**Unique Identifier (UDI) #**	

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* | 7. **If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(Exclude treatment of event)*
See additional page(s) for complete text.

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
Last Name: (b) (6) First Name: (b) (6)
Address: (b) (6)
City: (b) (6) State/Province/Region: (b) (6)
Country: US ZIP/Postal Code: (b) (6)
Phone #: (b) (6) E-mail: (b) (6)

2. **Health Professional?** ☐ Yes ☐ No
3. **Occupation**
4. **Also Reported to:** ☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☑

PLEASE TYPE OR USE BLACK INK

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

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 nasal 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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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:

September 20, 2016

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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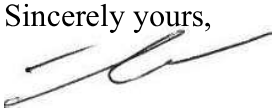
To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 198069.

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

Sincerely yours,



Lyle Canida, Pharm.D., M.S.
LCDR, U.S. Public Health Service
Branch Chief, Signals Management Branch
Division of Public Health Informatics & Analytics
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure

[Close]

FACTS Interface

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

Complainant Identification			
Name	(b) (6)	**Work Phone**	(b) (6)
Address	(b) (6)	**Home Phone**	(b) (6)
		Source POC Name	
City	(b) (6)	**Source Phone**	
State			
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 the 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
	Adverse Event Date	2015, 2016
	Notify EIO/EMOPS?	Yes
	Notification Date	08/01/2016
	Attended Health Professional?	No
	Required Hospitalization?	No
	Emergency Room/ Outpatient Visit?	No
	Reported Complaint To?	Other
	Need Additional/ FDA Contact?	
Remarks Reported to Panico Salon Owner.		

Complaint Symptoms		
Symptom Name	**Duration**	**Remarks**
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.

Product and Labeling			
Brand Name	Brazilian Blowout		
Product Name	Hair Straightener		
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	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 Desc**	
Warning Statement on Label?		**Warning Statements?**	
Preexisting Conditions?	No	**Treatment**	
Current Status			
Medical Diagnosis		**Medical Treatment**	
Remarks			

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

[Close]

October 24, 2016

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.

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

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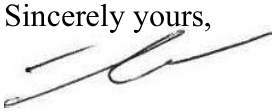
Sincerely yours,



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Enclosure

U.S. Department of Health and Human Services

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

Page _ of _

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

FDA USE ONLY
Triage unit
sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier
In confidence

2. Age at Time of Event, or Date of Birth:

3. Sex
☐ Female
☐ Male

4. Weight
_____ lb
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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)*
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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

4. Date of this Report *(mm/dd/yyyy)*
08/01/2016

5. Describe Event, Problem or Product Use Error

Caller wants to report an adverse event after a Brazilian Blowout Treatment. She has had these treatments in the past without problem. In 2015 she went the salon and was given treatment but the product was left on for three days. The salon person said the longer it's left on the straighter the hair gets. When the caller washed her hair she noticed hair right eyelashes were missing and that her hair damaged. Lesions appeared on legs. She ended up going to another salon which to cut off because was so much damage. For months the caller let her grow out again. And in April after consulting with stylist who assured her it was safe she received another Brazilian Blowout. She said she returned the first salon and received 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 Waiver releasing salon from responsibility. She said thinks product is not safe and believes it should be pulled from market.

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Brazilian Blowout
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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
(b) (6)

Phone #
(b) (6)

E-mail
(b) (6)

2. Health Professional?
☐ Yes ☐ No

3. Occupation

4. Also Reported to:
☐ Manufacturer
☐ User Facility
☐ Distributor/Importer

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

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