

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence #

546681

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 74 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 200 lb or _____ kg
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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: _____ ☐ Disability or Permanent Damage
 (mm/dd/yyyy)
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☒ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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

04/09/2014

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

04/11/2014

5. Describe Event, Problem or Product Use Error

On Wednesday April 9th I washed my hair 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)	5. Event Abated After Use Stopped or Dose Reduced?
#1 04/09/2014 -	#1 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
4. Diagnosis or Reason for Use (Indication)	8. Event Reappeared After Reintroduction?
#1 to condition hair	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
6. Lot #	7. Expiration Date
#1 02254JU36	#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		
APR 14 2014		
4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	<input type="checkbox"/> Health Professional
Serial #	Other #	<input type="checkbox"/> Lay User/Patient
		<input type="checkbox"/> 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?		
<input type="checkbox"/> Yes <input type="checkbox"/> 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@gmail.com	
2. Health Professional?	3. Occupation	4. Also Reported to:	
<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Manufacturer	
		<input type="checkbox"/> User Facility	
		<input type="checkbox"/> Distributor/Importer	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input type="checkbox"/>			

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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.

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597413

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 0	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight ____ lb or ____ kg
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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: _____ ☐ Disability or Permanent Damage
(mm/dd/yyyy)
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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

06/10/2013

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

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)	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	8. Event Reappeared After Reintroduction?
#1 Lichen planiplaruis	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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)	<input type="checkbox"/> Health Professional
Serial #	Other #	<input type="checkbox"/> Lay User/Patient
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?		
<input type="checkbox"/> Yes <input type="checkbox"/> 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:
<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input type="checkbox"/>		<input type="checkbox"/> User Facility
		<input type="checkbox"/> Distributor/Importer

5474/3

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

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

Enclosure

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)

CAERS 05/02/2014

Last Name: (b) (6)

Injury Incident, No Injury Information:

Victim is of No Hispanic/Latino origin?

Race: White

Other

Race/Ethnicity:

My Relationship Self to Victim:

Gender: Female

Age when 34 Years

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:

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

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

000002

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

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

Your Contact Information

First Name: (b) (6)

Last Name: (b) (6)

Address: (b) (6), United States

E-mail (b) (6)

Phone Number: (b) (6)

Consent

May we include 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:

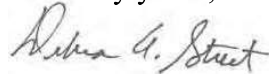
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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 # 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

MEDWATCHThe FDA Safety Information and
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adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence # 549390**A. PATIENT INFORMATION**

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event or Date of Birth: 30 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 140 lb or kg
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B. ADVERSE EVENT, PRODUCT PROBLEM OR ERRORCheck 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) 04/29/2014	4. Date of this Report (mm/dd/yyyy) 05/06/2014
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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		
6. Lot #	7. Expiration Date	
#1	#1	
#2	#2	
5. Event Abated After Use Stopped or Dose Reduced?		
#1 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		
8. Event Reappeared After Reintroduction?		
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply		
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		
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 <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other:
Catalog #	Expiration Date (mm/dd/yyyy)	
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? <input type="checkbox"/> Yes <input type="checkbox"/> 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 # (b) (6)		E-mail (b) (6)	
2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation	4. Also Reported to: <input type="checkbox"/> Manufacturer <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input checked="" type="checkbox"/>			

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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: Seasonal

Important Information: None

RX Meds: Bupropion, Lamotrigene, trinessa

OTC Meds: Glucosamine

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sequence #

549495

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 27 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 153 lb or _____ kg
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(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)

04/25/2014

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

05/07/2014

5. Describe Event, Problem or Product Use Error

Used a keratin hair smoothing treatment 2 weeks 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

6. Lot #

#1

#2

7. Expiration Date

#1

#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****3. Manufacturer Name, City and State****4. Model #****Lot #****Catalog #****Expiration Date (mm/dd/yyyy)****Serial #****Other #****6. If Implanted, Give Date (mm/dd/yyyy)****7. If Expanted, 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?☐ 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:** ☐

549495

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

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product use errors**FDA USE ONLY**Triage unit
sequence #

550620

A. PATIENT INFORMATION

1. Patient Identifier #16	2. Age at Time of Event or Date of Birth: 43 Years	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 165 lb or kg
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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: _____ ☐ Disability or Permanent Damage
 (mm/dd/yyyy)
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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

05/16/2014

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

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

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**

CTU

3. Manufacturer Name, City and State

MAY 19 2014

4. Model #**Lot #****Catalog #****Expiration Date (mm/dd/yyyy)****Serial #****Other #****5. Operator of Device**

- ☐ Health Professional
☐ Lay User/Patient
☐ 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 #

(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:☐

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)

550620

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:

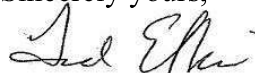
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors

FDA USE ONLY

Triage unit
sequence # 552932**A. PATIENT INFORMATION**

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event or Date of Birth: 61 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 180 lb or kg
---	---	---	---------------------------------

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERRORCheck all that apply:
1. ☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine2. 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) 05/16/2014	4. Date of this Report (mm/dd/yyyy) 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 Tresemmé'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 87 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: Tresemmé

#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 about 1 month		
#2		
4. Diagnosis or Reason for Use (Indication)		
#1 Temporarily straighten curly, frizzy hair.		
#2		
6. Lot #	7. Expiration Date	
#1	#1	
#2	#2	
5. Event Abated After Use Stopped or Dose Reduced?		
#1 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		
8. Event Reappeared After Reintroduction?		
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply		
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 #		
Catalog #		
Expiration Date (mm/dd/yyyy)		
Serial #		
Other #		
5. Operator of Device		
<input type="checkbox"/> Health Professional		
<input type="checkbox"/> Lay User/Patient		
<input type="checkbox"/> 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?		
<input type="checkbox"/> Yes <input type="checkbox"/> 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:
<input type="checkbox"/> Yes <input type="checkbox"/> No		<input checked="" type="checkbox"/> Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input type="checkbox"/>		<input type="checkbox"/> User Facility
		<input type="checkbox"/> Distributor/Importer

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 nausea 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: Nicardipine 80, Systolic

OTC Meds: Multiple vitamin, Olive leaf extract, Red yeast rice, Sam-E (400 mg), Ester-C (500 mg), Glucosamine/Chondroitin (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	(b) (6)		
Zip	(b) (6)		
Province			
Country	US		
Mail Code			

Complaint / Injury

Complaint Description	Adverse Event Result	Non-serious Injuries/ Illness
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. Complainant's 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 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 hair's 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 hair's youthful look and texture. ?Provides the ultimate anti-aging boost ?Infused with vital Keratin amino acids and damage-reversing Ceramides. ?Reduces frizz up to 95%. ?100% true Formaldehyde-Free and Aldehyde-Free system ?Leaves hair full-bodied and frizz free for up to 3 months.

Complaint Symptoms

000001

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

Health Care Professional

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

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	

000002

Remarks	
First use of product; complainant has allergies to shrimp, dustmites, cats; complainant administered inhaler	
Adverse Events	
There is no adverse event information listed for this consumer complaint report.	

[\[Close\]](#)

June 24, 2014

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

To Whom It May Concern:

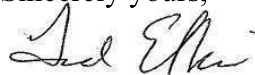
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors

FDA USE ONLY

Triage unit
sequence #

554723

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 25 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 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)

06/18/2014

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

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 FDA's "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)		5. Event Abated After Use Stopped or Dose Reduced?
#1		#1 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

4. Diagnosis or Reason for Use (Indication)		8. Event Reappeared After Reintroduction?
#1		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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		
CTU JUN 23 2014		
4. Model #	Lot #	5. Operator of Device
		<input type="checkbox"/> Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	<input type="checkbox"/> Lay User/Patient
		<input type="checkbox"/> 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?		
<input type="checkbox"/> Yes <input type="checkbox"/> 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:
<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input type="checkbox"/>		<input type="checkbox"/> User Facility
		<input type="checkbox"/> Distributor/Importer

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	Adverse Event Result	Non-serious Injuries/ Illness
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 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
			000001

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

Manufacturer/Distributor

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

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-ventilated 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.

[\[Close\]](#)

000002

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence # 557268**A. PATIENT INFORMATION**

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event or Date of Birth: 39 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 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)
07/14/20144. Date of this Report (mm/dd/yyyy)
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 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		
8. Event Reappeared After Reintroduction?		
#1 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other:
Catalog #	Expiration Date (mm/dd/yyyy)	
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? <input type="checkbox"/> Yes <input type="checkbox"/> 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 # (b) (6)	E-mail (b) (6)	
2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation	4. Also Reported to: <input type="checkbox"/> Manufacturer <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input type="checkbox"/>		

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

557268

... 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

557268

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: Clindamycin

Important Information:

RX Meds: Levothyroxine 75mcg

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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence #

561719

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 39 years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight ____ lb or ____ kg
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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)
☐ 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) 08/20/2014
 4. Date of this Report (mm/dd/yyyy) 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 #

#1

#2

7. Expiration Date

#1

#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

AUG 22 2014

4. Model #**Lot #****Catalog #****Expiration Date (mm/dd/yyyy)****Serial #****Other #****5. Operator of Device**

- ☐ Health Professional
☐ Lay User/Patient
☐ 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?☐ 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: ☐

561714

B.5. Describe Event or Problem (continued)

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

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

None

561714

561714

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

Race:--

Medical Conditions: None

Allergies: None

Important Information: Sensitive to chemicals

RX Meds: none

OTC Meds: None

August 26, 2014

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

To Whom It May Concern:

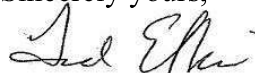
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**A. PATIENT INFORMATION**

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 51 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 145 lb or _____ kg
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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: _____ ☐ Disability or Permanent Damage
(mm/dd/yyyy)
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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

08/22/2014

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

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

#1

#2

Frequency**Route**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

6. Lot #

#1

#2

7. Expiration Date

#1

#2

5. Event Abated After Use
Stopped or Dose Reduced?#1 ☐ Yes ☒ No ☐ Doesn't
Apply#2 ☐ Yes ☐ No ☐ Doesn't
Apply8. 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 #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Other #

5. Operator of Device

☐ Health Professional☐ Lay User/Patient☐ 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 #

(b) (6)

E-mail

(b) (6)

2. Health Professional?

☐ Yes ☐ No

3. Occupation

4. Also Reported to:

☐ Manufacturer☐ User Facility☐ Distributor/Importer5. If you do NOT want your identity disclosed
to the manufacturer, place an "X" in this box: ☐

B.5. Describe Event or Problem (continued)

561940

I received a Keratin hair treatment-Brazilian Blowout-this afternoon. This was my second treatment at this salon and I hadn't experienced any side effects before. My stylist (both times) assured me that the product he was using is formaldehyde-free. (He used the same product both times) This time after he applied the treatment, my eyes began to water, and soon my nose was running, my throat was tingling and I began coughing. At one point, he gave me a mask (but not at first) and then after I began coughing, he brought out a fan. My symptoms subsided 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 formaldehyde-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.

561940

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:

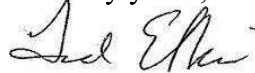
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errorsPage 1 of 2

FDA USE ONLY

Triage unit
sequence #

178972

2153

A. PATIENT INFORMATION

1. Patient Identifier In confidence	2. Age at Time of Event, or Date of Birth: (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 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) ☐ 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) 8-30-2014	4. Date of this Report (mm/dd/yyyy) 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 dioxide, formadahye 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

#1

#2

7. Expiration Date

#1

#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

Catalog

Expiration Date (mm/dd/yyyy)

Serial

Other

5. Operator of Device

- ☐ Health Professional
☐ Lay User/Patient
☐ 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

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: ☐

September 15, 2014

Yehia Company
1455 East 53rd
Chicago, Illinois 60018

To Whom It May Concern:

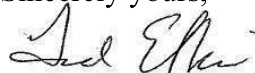
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

000001

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

Initial Evaluation / 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.

[\[Close\]](#)

000002

October 09, 2014

Cadiveu Cosméticos
Martim De Sa 75
Sao Paulo,
Brazil

To Whom It May Concern:

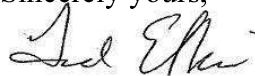
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Sincerely yours,



Ted Elkin
Director
Office of Analytics and Outreach
Center for Food Safety
and Applied Nutrition

Enclosure

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence #

564025

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event or Date of Birth: 29 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 137 lb or kg
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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) 08/15/2014	4. Date of this Report (mm/dd/yyyy) 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 #

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

5. Event Abated After Use Stopped or Dose Reduced?

#1	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

8. Event Reappeared After Reintroduction?

#1	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 #****Catalog #****Expiration Date (mm/dd/yyyy)****Serial #****Other #****5. Operator of Device**

☐ Health Professional
☐ Lay User/Patient
☐ 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 Million
 Address:

City:

State: -- ZIP:

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:

☐

564025

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

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

564025

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

Biopsy of neck lesion: eczematous dermatitis

564025

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, Globetrol

OTC Meds: Hydrocortisone, Benadryl

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence # **578527****A. PATIENT INFORMATION**

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight ____ lb or ____ kg
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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)
01/07/20154. Date of this Report (mm/dd/yyyy)
01/08/20155. 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: 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 #

#1

#2

7. Expiration Date

#1

#2

5. Event Abated After Use
Stopped or Dose Reduced?#1 ☐ Yes ☒ No ☐ Doesn't
Apply#2 ☐ Yes ☐ No ☐ Doesn't
Apply8. 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 #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Other #

5. Operator of Device

☐ Health Professional☐ Lay User/Patient☐ 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 #

(b) (6)

E-mail

(b) (6)

2. Health Professional?

☐ Yes ☐ No

3. Occupation

4. Also Reported to:

☐ Manufacturer☐ User Facility☐ Distributor/Importer5. If you do NOT want your identity disclosed
to the manufacturer, place an "X" in this box: ☐

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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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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence # **579258****A. PATIENT INFORMATION**

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event or Date of Birth: (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 148 lb or kg
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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)

01/08/2015

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

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 #

#1

#2

7. Expiration Date

#1

#2

5. Event Abated After Use
Stopped or Dose Reduced?#1 ☐ Yes ☒ No ☐ Doesn't
Apply#2 ☐ Yes ☐ No ☐ Doesn't
Apply8. 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 <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other:
Catalog #	Expiration Date (mm/dd/yyyy)	
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 #

(b) (6)

E-mail

(b) (6)

2. Health Professional?

☐ Yes ☐ No

3. Occupation

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

4. Also Reported to:

- ☒ Manufacturer
☐ User Facility
☐ Distributor/Importer

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)*

No tests taken at this point

579258

579258

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: 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, AdvairClear, 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

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Sincerely yours,



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

Enclosure

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence # 583819**A. PATIENT INFORMATION**

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 162 lb or _____ kg
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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)

02/11/2015

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

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:

2. Dose or Amount**Frequency****Route**

#1			
#2			

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

#1		5. Event Abated After Use Stopped or Dose Reduced? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

4. Diagnosis or Reason for Use (Indication)

#1 straighten hair	8. Event Reappeared After Reintroduction? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

6. Lot #

#1	7. Expiration Date #1	9. NDC # or Unique ID
#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**Serial #****Other #**☐ 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 #

(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: ☐

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.

000002
29/5

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

Race: White

Medical Conditions: low thyroid

Allergies: none

Important Information: none

RX Meds: 75 mg levothyroxine daily

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

583819

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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors

CFSAN

FDA USE ONLY

Triage unit
sequence #

590205

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 36 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 215 lb or kg
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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)
03/29/2015

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

6. Lot #

#1

#2

7. Expiration Date

#1

#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 - 1 2015

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

(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:**☐

590205

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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence #

594169

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 59 Years	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight ____ 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: _____ ☒ Disability or Permanent Damage
 (mm/dd/yyyy)
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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

04/21/2015

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

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)**

#1 04/21/2015 -

#2

4. Diagnosis or Reason for Use (Indication)

#1 Stylist indicated it smooths hair

#2

6. Lot #

#1

#2

7. Expiration Date

#1

#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

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Other #

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

☐ Yes ☐ No

3. Occupation

4. Also Reported to:

☐ Manufacturer☐ User Facility☐ Distributor/Importer5. If you do NOT want your identity disclosed
to the manufacturer, place an "X" in this box: ☒

594169

B.5. Describe Event or Problem (continued)

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

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

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, 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)

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors

CFSAN

FDA USE ONLY

Triage unit
sequence #

602433

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 44 Years (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight lb or 78 kg
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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)

06/16/2015

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

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)

#1 06/16/2015 - 06/16/2015

#2

4. Diagnosis or Reason for Use (Indication)

#1 Hair treatment

#2

6. Lot

#1

#2

7. Expiration Date

#1

#2

5. Event Abated After Use
Stopped or Dose Reduced?#1 ☒ Yes ☐ No ☐ Doesn't Apply#2 ☐ Yes ☐ No ☐ Doesn't Apply8. 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

JUN 24 2015

3. Manufacturer Name, City and State

4. Model

Lot

Catalog

Expiration Date (mm/dd/yyyy)

Serial

Other

5. Operator of Device

☐ Health Professional☐ Lay User/Patient☐ 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

(b) (6)

E-mail

(b) (6)

2. Health Professional?

☐ Yes ☐ No

3. Occupation

4. Also Reported to:

☐ Manufacturer☐ User Facility☐ Distributor/Importer5. If you do NOT want your identity disclosed
to the manufacturer, place an "X" in this box: ☐

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:

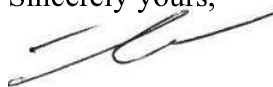
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FDA USE ONLY**Triage unit
sequence #

607597

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 40 Years	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 135 lb or _____ kg
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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)

07/08/2015

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

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)

#1 07/08/2015 -

#2

4. Diagnosis or Reason for Use (Indication)

#1 hair straightening and reduce frizz product

#2

6. Lot

#1 120015F2

#2

7. Expiration Date

#1

#2

5. Event Abated After Use
Stopped or Dose Reduced?#1 ☒ Yes ☐ No ☐ Doesn't Apply#2 ☐ Yes ☐ No ☐ Doesn't Apply8. 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 28 2015

4. Model #	Lot #	5. Operator of Device <input type="checkbox"/> Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	<input type="checkbox"/> Lay User/Patient
Serial #	Other #	<input type="checkbox"/> 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

(b) (6)

E-mail

(b) (6)

2. Health Professional?

☐ Yes ☐ No

3. Occupation

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

4. Also Reported to:

- ☒ Manufacturer
☐ User Facility
☐ Distributor/Importer

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:

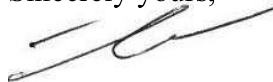
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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

Page ____ of ____

FDA USE ONLYTriage unit
sequence #

071538

A. PATIENT INFORMATION

1. Patient Identifier In confidence	2. Age at Time of Event, or Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> 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)

10/06/2015

5. Describe Event, Problem or Product Use ErrorReaction 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

4. Diagnosis or Reason for Use (Indication)

#1

#2

6. Lot #

#1

#2

7. Expiration Date

#1

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	<input type="checkbox"/> Health Professional
Serial #	Other #	<input type="checkbox"/> Lay User/Patient
		<input type="checkbox"/> 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 #

831-524-2855

E-mail

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:**☐

PLEASE TYPE OR USE BLACK INK

February 04, 2016

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

To Whom It May Concern:

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

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

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

Sincerely yours,



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

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.

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LCDR, U.S. Public Health Service
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Division of Public Health Informatics &
Analytics
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

FDA USE ONLY

Trace 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)	2. Age 28 <input checked="" type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 08 Feb 1925)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 140 <input checked="" type="checkbox"/> lb <input type="checkbox"/> kg
----------------------------------	---	---	---

5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input checked="" type="checkbox"/> Not Hispanic/Latino	5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> 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 Keratin Cure Chocolate max v1	#1 - NDC # or Unique ID
---	-------------------------

#1 - Manufacturer/Compounder Keratin Cure	#1 - Lot #
--	------------

#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 -

5. Diagnosis or Reason for Use (indication)

#1 straightens hair

#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

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device

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? ☐ 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 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)

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

Trace 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)	2. Age <input checked="" type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) 28 or Date of Birth (e.g., 08 Feb 1925)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 140 <input checked="" type="checkbox"/> lb <input type="checkbox"/> kg
-------------------------------	--	---	--

5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input checked="" type="checkbox"/> Not Hispanic/Latino	5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> 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 Keratin Cure Chocolate max v1	#1 - NDC # or Unique ID
--	-------------------------

#1 - Manufacturer/Compounder Keratin Cure	#1 - Lot #
--	------------

#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? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> No	7. Is the Product Over-the-Counter? #1 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> No
---	--

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

Catalog #

Serial #

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: First Name:
 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

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)



KÉRATIN MIAMI **CURE**
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



'16 JL 2

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>.

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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

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 #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)	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 08 Feb 1925) (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 128 <input checked="" type="checkbox"/> lb <input type="checkbox"/> 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) migraine, 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
Brazilian Blowout

#1 - NDC # or Unique ID

#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		Applied
#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)
in salon smoothing treatment

#1

#2

9. Event Abated After Use
Stopped or Dose Reduced?#1 ☐ Yes ☒ No ☐ Doesn't
apply
#2 ☐ Yes ☐ No ☐ Doesn't
apply10. Event Reappeared After
Reintroduction?#1 ☒ Yes ☐ No ☐ Doesn't
apply
#2 ☐ Yes ☐ No ☐ Doesn't
apply6. Is the Product
Compounded?#1 ☐ Yes ☒ No
#2 ☐ Yes ☐ No7. Is the Product
Over-the-Counter?#1 ☒ Yes ☐ No
#2 ☐ Yes ☐ No

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

#2

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

2b. Procode

3. Manufacturer Name, City and State

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/Importer5. If you do NOT want your identity disclosed
to the manufacturer, please mark this box: ☐

B.5. Describe Event or Problem (continued)

I am a salon professional who is working in a salon that provides Brazilian blowout services in a non ventilated space and insufficient training in application of this product. I have been exposed to formaldehyde 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)

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 #

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)	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 08 Feb 1925) (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 128 <input checked="" type="checkbox"/> lb <input type="checkbox"/> 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) migraine, 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
Brazilian Blowout

#1 - NDC # or Unique ID

#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		Applied
#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)
in salon smoothing treatment

#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

6. Is the Product
Compounded?#1 ☐ Yes ☒ No#2 ☐ Yes ☐ No7. Is the Product
Over-the-Counter?#1 ☒ Yes ☐ No#2 ☐ Yes ☐ No

8. Expiration Date (dd-mmm-yyyy)

#1

#2

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

2b. Procode

3. Manufacturer Name, City and State

MAY 20 2016

4. Model #

Lot #

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

B.5. Describe Event or Problem (continued)

I am a salon professional who is working in a salon that provides Brazilian blowout services in a non ventilated space and insufficient training in application of this product. I have been exposed to formaldehyde 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)

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 until
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)	2. Age <input checked="" type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) 30 <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 115 <input checked="" type="checkbox"/> lb <input type="checkbox"/> kg
or Date of Birth (e.g., 08 Feb 1925)			

In Confidence

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 Profess	

#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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
#2	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply

10. Event Reappeared After Reintroduction?

#1	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
#2	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply

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

4. Model #**Lot #****Catalog #****Expiration Date (dd-mmm-yyyy)****Serial #****Unique Identifier (UDI) #****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: ☐

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: Ciclepirox topical cream

OTC Meds: None

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 until
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)	2. Age <input checked="" type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) 30 <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 115 <input checked="" type="checkbox"/> lb <input type="checkbox"/> kg
or Date of Birth (e.g., 08 Feb 1925)			

In Confidence

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 Brazilian Blowout Acai Professi	#1 - NDC # or Unique ID
---	-------------------------

#1 - Manufacturer/Compounder Brazilian Blowout	#1 - Lot #
---	------------

#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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
#2	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply

10. Event Reappeared After Reintroduction?

#1	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
#2	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply

6. Is the Product Compounded?#1 ☐ Yes ☒ No#2 ☐ Yes ☐ No**7. Is the Product Over-the-Counter?**#1 ☒ 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****4. Model #****Lot #****Catalog #****Expiration Date (dd-mmm-yyyy)****Serial #****Unique Identifier (UDI) #****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

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: Ciclepirox 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

MEDWATCHFor VOLUNTARY reporting of
adverse events, product problems and
product use errorsThe FDA Safety Information and
Adverse Event Reporting Program

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)	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 08 Feb 1925) (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 144 <input checked="" type="checkbox"/> lb <input type="checkbox"/> kg
----------------------------------	---	---	---

5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input checked="" type="checkbox"/> Not Hispanic/Latino	5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input checked="" type="checkbox"/> White <input type="checkbox"/> 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) 20-Jun-2016	4. Date of this Report (dd-mmm-yyyy) 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 Brazilian blowout acai anti frizz, 12 350 ml	#1 - NDC # or Unique ID
#1 - Manufacturer/Compounder GIB LLC	#1 - Lot # 9947150
#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 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	#1 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name		2b. Procode CTU
2. Common Device Name		
3. Manufacturer Name, City and State JUL -5 2016		
4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (dd-mmm-yyyy)	<input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> 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 PRODUCTSProduct 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? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation	4. Also Reported to: <input type="checkbox"/> Manufacturer/Compounder <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: <input checked="" type="checkbox"/>		1 of 2

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 bactrim

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:

MEDWATCHFor VOLUNTARY reporting of
adverse events, product problems and
product use errorsThe FDA Safety Information and
Adverse Event Reporting Program

FDA USE ONLY

Triage unit
sequence #FDA Rec.
Date

6666273

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)	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 08 Feb 1925) (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 144 <input checked="" type="checkbox"/> lb <input type="checkbox"/> 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)

20-Jun-2016

4. Date of this Report (dd-mmm-yyyy)

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 Brazilian blowout acai anti frizz, 12.50 ml	#1 - NDC # or Unique ID
#1 - Manufacturer/Compounder GIB LLC	#1 - Lot # 9947150
#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

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?

- #1
- ☒
- Yes
- ☐
- No
-
- #2
- ☐
- Yes
- ☐
- No

7. Is the Product
Over-the-Counter?

- #1
- ☒
- 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

CTU

3. Manufacturer Name, City and State

JUL -5 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)

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.

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 bactrim

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:

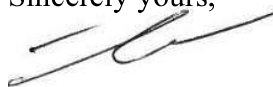
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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 # 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	(b) (6)		
Zip	(b) (6)		
Province			
Country	US		
Mail Code			

Complaint / Injury**Complaint Description**

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

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 NUrstiti@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:

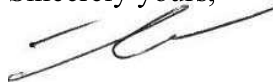
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We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found 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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 199664.

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

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errorsPage 1 of 1**FDA USE ONLY**Triage unit
sequence #**A. PATIENT INFORMATION**

1. Patient Identifier In confidence	2. Age at Time of Event, or Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> 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

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

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 #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Other #

5. Operator of Device

☐ Health Professional☐ Lay User/Patient☐ 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/Importer5. If you do NOT want your identity disclosed
to the manufacturer, place an "X" in this box: ☐