MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (b) (6)
2. Age at Time of Event or Date of Birth: 74 Years
3. Sex: (b) Female
4. Weight: 200 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. Adverse Event: Yes
   - Product Problem (e.g., defects/malfunctions)
   - Product Use Error: No

2. Outcomes Attributed to Adverse Event:
   - Death: (mm/dd/yyyy) 04/09/2014
   - Disability or Permanent Damage
   - Life-threatening
   - Congenital Anomaly/Birth Defect
   - Hospitalization, Initial or Prolonged
   - Other Serious (Importantly Medical Event)
   - 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 8th, I washed my hair with Ilalion
Evershine 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 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 noticed that my face was 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 neck had a rash between my shoulder
blades and down.

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: Keratin Infusion
   Strength:
   Manufacturer: Suave

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
... 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 4:15 (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.
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
2. Age at Time of Event or Date of Birth: (b)(6)
3. Sex
   - Female
   - Male
4. Weight
   - (b)(6)
5. Date of Event (mm/dd/yyyy) 06/10/2013
6. Date of this Report (mm/dd/yyyy) 04/18/2014

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. Use Error
4. Problem with Different Manufacturer of Same Medicine
5. Outcomes Attributed to Adverse Event
   - Death (mm/dd/yyyy)
   - Disability or Permanent Damage
   - Congenital Anomaly/Birth Defect
   - Hospitalization - initial or prolonged
   - Other Serious (Important Medical Events)
6. Required Intervention to Prevent Permanent Impairment/Damage (Devices)

C. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
6. Operator Type
7. If Implanted, Give Date (mm/dd/yyyy)
8. If Explanted, Give Date (mm/dd/yyyy)
9. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   - Yes
   - No
10. If Yes to Item No. 9, Enter Name and Address of Reprocessor

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

E. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   - Copolla
   - Copolla
   - Manufacturer:
2. E-mail #

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
   - Yes
   - No
   - Returned to Manufacturer:

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   - Copolla
   - Copolla
   - Manufacturer:
2. E-mail #

F. REPORTER (See confidentiality section on back)
1. Name and Address
2. Health Professional
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:
6. If you do NOT want your identity disclosed to the next manufacturer, place an "X" in this box:

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
... 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 into 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/oi/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: 11440557A
Report Number: 20140430-43443-2147444968
Report Submitted Date:

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 Information: Incident, No Injury
Victim is of Hispanic/Latino origin?
Race: White
Other Race/Ethnicity:

My Relationship to Victim:
Gender: Female
Age when 34 Years

CPSC does not guarantee the accuracy, completeness, or adequacy of the contents of the Publicly Available Consumer Product Safety Information Database on SaferProducts.gov, particularly with respect to information submitted by people outside of CPSC,
incident occurred:
Address: (b)(6)
E-mail: (b)(6)
Phone Number: (b)(6)

Product Details

Product: The first product I used was Suave "keratin infusion heat defense leave in conditioner" A few 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:
Product Type: Shampoo and Conditioner
Brand Name: Suave
Manufacturer / Unilever
Importer / Private Labeler
Name:
Model Name or Number: 83223367, 83223359, 83176479
Serial Number: 01134JU36, 01044JU36
Date Manufactured:
Manufacturer Date Code:
Manufacturer Address:
Manufacturer Website URL:
Manufacturer Phone Number:
Retailer: Walmart
Retailer State: Lansing, MI

Additional Details

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

I still have the product in my possession.

The product was damaged before the incident.

The product was modified before the incident.

Have you contacted the manufacturer?
If not, do you 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? Yes, you may release my name and contact information to the product manufacturer /importer / private labeler identified in your Report?

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 website, 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
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

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

A. PATIENT INFORMATION
1. Patient Identifier
2. Age at Time of Event or Date of Birth:
   (b) 30 Years
   (b) 6
3. Sex
   □ Female
   □ Male
4. Weight
   140 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine

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

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

5. Describe Event, Problem or Product Use Error
   Get a Brazilian blowout and was told formaldehyde only affects the hairdresser. I have 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 #7 below.

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
   □ Yes  □ No  □ Returned to Manufacturer

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   Name: Formaldehyde
   Strength: brazilian blowout
   Manufacturer:

2. Dose or Amount
   #1
   #2

3. Dates of Use (if unknown, give duration from to (or best estimate)
   #1 04/23/2014
   #2

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

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

6. Lot #
   #1
   #2

7. Expiration Date
   #1
   #2

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

9. NDC # or Unique ID
   □ Yes  □ No  □ Doesn't Apply

E. SUSPECT MEDICAL DEVICE
1. Brand Name
   CTV

2. Common Device Name
   MAY - 7 2014

3. Manufacturer Name, City and State

4. Model #
   Lot #
5. Operator of Device
   □ Health Professional
   □ Lay User/Invent
   □ Other:

   Serial #
   □ Other #

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

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   #1 Yes  #2 No

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (excluding 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
   □ Yes  □ No
4. Also Reported to:
   □ Manufacturer
   □ User Facility
   □ Distributor/Importer

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
B.7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic renal dysfunction, etc.) (continued)

Medical Conditions: None
----------
Allergies: Seasonal
----------
Important Information: None
----------
RX Meds: Rupitapon, Lamotrigine, trinessa
----------
GTC Meds: Glucosamine
### A. PATIENT INFORMATION
1. **Patient Identifier**
   - (b) (6) [Redacted]
2. **Age at Time of Event or Date of Birth:**
   - 27 Years
3. **Sex:**
   - [✓] Female
   - [ ] Male
4. **Weight:**
   - 153 lb
   - [ ] kg

### B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. **Outcomes Attributed to Adverse Event**
   - [ ] Death
   - [ ] 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 (Devices)
2. **Date of Event**
   - 04/25/2014
3. **Date of this Report**
   - 05/07/2014
4. **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.

### E. SUSPECT MEDICAL DEVICE
1. **Brand Name**
2. **Common Device Name**
3. **Manufacturer Name, City and State**
4. **Model #**
5. **Lot #**
6. **Operator of Device**
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] Other
7. **Catalog #**
8. **Expiration Date**
   - (mm/dd/yyyy)
9. **If Implanted, Give Date**
   - (mm/dd/yyyy)
10. **If Explanted, Give Date**
    - (mm/dd/yyyy)

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

### G. REPORTER (See confidentiality section on back)
1. **Name and Address**
   - Name: [Redacted]
   - Address: [Redacted]
2. **City, State, ZIP**
   - [Redacted]
3. **Phone #**

### FORM FDA 3500 (1/09)
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

---

**Notices and Instructions:**
- For VOLUNTARY reporting of adverse events, product problems and product use errors.
- FDA USE ONLY.
- Please type or use black ink.
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: Phenetermine 37.5mg
OTC Meds: 812
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier: 6552312
2. Age at Time of Event or Date of Birth: 63 years
3. Sex: Female
4. Weight: 165 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. Adverse Event: Yes
2. Product Problem (e.g., defects/malfunctions): Yes
3. Product Use Error: No

3. Outcomes Attributed to Adverse Event
   - Death: No
   - Disability or Permanent Damage: No
   - Life-threatening: Yes
   - Congenital Anomaly/Birth Defect: No
   - Hospitalization: Yes
   - Other Serious (Imminent Medical Events): No
   - Required Interventions to Prevent Permanent Impairment/Damage (Devices): No

4. Date of Event (mm/dd/yyyy): 05/16/2014
5. Date of this Report (mm/dd/yyyy): 05/18/2014
6. Relevant Tests/Laboratory Data, Including Dates
   - For additional information see B7 below.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, kidney, liver, kidney, or other conditions): White

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA): Yes
Returned to Manufacturer: No

D. SUSPECT PRODUCT(S)
1. Name: Global Keratin
   Strength: Strong

2. Name: Global Keratin
   Strength: Weak

E. SUSPECT MEDICAL DEVICE
1. Brand Name: Citu
   Dated: 05/19/2014
2. Common Device Name: Keratin conditioning treatment
3. Manufacturer Name, City and State: Global Keratin, Inc., 123 Main St, Anytown, CA 90210
4. Model #: 12345
   Serial #: 67890
   Other #: None
5. Operated by Device: No
   Lay User: No
   Other: No
6. If implanted, Give Date (mm/dd/yyyy): No
   If implanted, Give Date (mm/dd/yyyy): No
7. Is this a Single-use Device that was Reprocessed and Reused on a Patient?: No
8. If Yes to Item No. 6, Enter Name and Address of Reprocessor: None

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

G. REPORTER (See confidentiality section on back)
1. Name and Address: John Doe, 456 Main St, Anytown, CA 90210
   Phone #: (555) 123-4567
   E-mail: johndoe@example.com
2. Health Professional?: Yes
3. Occupation: Nurse
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: Yes

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event:

000001
... 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)
Medical Conditions: None

Allergies: None

Important Information: Non-smoker, no health problems

RX Meds: Lesapre

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 into 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
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier [ ]
2. Age at Time of Event or Date of Birth:
   a) Years [ ]
   b) (b) [ ]
   or [ ]
3. Sex: [ ] Male
   [ ] Female
4. Weight: [ ] 180 lb
   or [ ] kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply.
1. [ ] Adverse Event
   [ ] Product Problem (e.g., defects, malfunctions)
   [ ] Product Use Error
   [ ] Problem with Different Manufacturer of Same Medicine
   [ ] Other

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   [ ] Death: (mm/dd/yyyy) [ ]
   [ ] Disability or Permanent Damage
   [ ] Life-threatening
   [ ] Congestive Anomaly/Birth Defect
   [ ] Congenital Anomaly/Birth Defect
   [ ] Other Serious or Important Medical Events
   [ ] Other
   [ ] Required Intervention to Prevent Permanent Impairment/Damage (Device)

3. Date of Event (mm/dd/yyyy) [ ] 05/16/2014
4. Date of Last Event (mm/dd/yyyy) [ ] 06/04/2014

5. Describe Event, Problem or Product Use Error
   I am a 60 year old white female who was born with
   thick curly, frizzy hair. I purchased Treacoma'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 3 weeks and my hair
   dresser was very alarmed at the noticeable hair loss I
   have experienced.

6. Relevant Test/Analysis/Procedures, including Diagnoses
   Recent blood lab...

7. Other Relevant History, including Preexisting Medical Conditions (e.g.,
   allergies, race, pregnancy, smoking and alcohol use, environmenal problems, etc.)
   Race: White
   For additional information see #7 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 System
   Manufacturer: Treacoma

   #2 Name: [ ]
   Strength: [ ]
   Manufacturer: [ ]

E. SUSPECT MEDICAL DEVICE
1. Brand Name [ ]
2. Common Device Name [ ]
3. Manufacturer Name, City and State [ ]
4. Model # [ ]
5. Lot # [ ]
6. Serial # [ ]
7. Expiration Date (mm/dd/yyyy) [ ]
8. If Implanted, Give Date (mm/dd/yyyy) [ ]
9. If Explanted, Give Date (mm/dd/yyyy) [ ]

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: [ ]
   Address: [ ]

2. Health Professional? [ ]
3. Occupation: [ ]
4. Also Reported to:
   [ ] Yes
   [ ] No

5. If you do NOT want your identity disclosed
   to the manufacturer, place an "X" in this box: [ ]
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.
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic or renal dysfunction, etc.) (continued)

Medical Conditions: High Blood Pressure

Allergies: None

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

RX Medications: No. Systolic

OTC Medications: Multiple vitamins, Olive leaf extract, Red yeast rice, 3x ono (400 mg), Ester-C (1000 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 into 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
FACTS Interface

FACTS Complaint #134206 (CAERS #177161)

Complaint Date: 05/17/2013
Complaint Source: Consumer
Accomplishing District: FLA-DO
Complaint Status: Archived
How Received: Telephone

Complainant Identification
Name: (b) (6)
Address: (b) (6)
City: (b) (6)
State: (b) (6)
Zip: (b) (6)
Province: (b) (6)
Country: US
Mail Code: 

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

Need Additional/ FDA Contact?

Complaint Description
Complaint visited her hair salon on 9/16/2013 for a Smoothing Therapy Keratin complex hair treatment. Complainant states product used to be Coppola Keratin treatment which she states contained formaldehyde, but is now just Smoothing Therapy Keratin Complex. Before product was applied, complainant questioned her hairdresser as to whether or not the product contained formaldehyde. The hairdresser gave the bottle to complainant to read the ingredients and no formaldehyde was listed. As soon as the product was applied both the hairdresser and complainant experienced burning/stinging eyes. The smoothing process takes 3 hours and then the hair is flat ironed. Complainant states that with 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 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, dustmotes and cats). She is a nurse and was unable to go to work today. Complainant stated 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.

Remarks
Complaint contacted Poison Control; Coponon Enterprises 888-409-4445. Complainant was given Keratin Care Shampoo and Conditioner by hairdresser for follow-up use after treatment. From www.petercoppola.com website: Rewind the strands of time with the new Coppola Keratin Treatment, Keratin and Ceramide, Formaldehyde-Free and Aldehyde-Free Treatment. This versatile treatment doesn't just smooth hair; it safely provides the ultimate anti-aging boost, adds volume and restores hairs youthful look and texture for a minimum of 3 months. The sophisticated formula uses the highest quality ingredients combined with a low pH mechanism to soften and smooth every hair type without the concern of harmful chemicals. Infused with vital Keratin amino acids and damage-reversing Ceramides. The new Coppola Keratin Treatment is part of the Peter Coppola Keratin Concept collection. Features: ?Adds volume and restores hairs youthful look and texture. ?Provides the ultimate anti-aging boost ?Infused with vital Keratin amino acids and damage-reversing Ceramides. ?Reduces frizz up to 95%. ?100% true Formaldehyde-Free and Aldehyde-Free system ?Leaves hair full-bodied and frizz free for up to 3 months.

Complaint Symptoms

000001

<table>
<thead>
<tr>
<th>Symptom Name</th>
<th>Duration</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIVa (urticaria, welts)</td>
<td>null</td>
<td>null</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>null Hour(s)</td>
<td>Burning/stinging of eyes</td>
</tr>
<tr>
<td>Vomiting</td>
<td>null Hour(s)</td>
<td>multiple times; improved</td>
</tr>
<tr>
<td>Nausea</td>
<td>null</td>
<td>null</td>
</tr>
<tr>
<td>Changes in skin and nail coloration (cyanosis, flushing)</td>
<td>null Hour(s)</td>
<td>Pale, colorless, lips were white</td>
</tr>
<tr>
<td>NEC - Identify in Remarks</td>
<td>null</td>
<td>null</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>null</td>
<td>null</td>
</tr>
</tbody>
</table>

**Health Care Professional**

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

**Product and Labeling**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Coppola</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>Keratin Complex Smoothing Therapy</td>
</tr>
<tr>
<td>FDA Product Code</td>
<td>53ED03</td>
</tr>
<tr>
<td>UPC Code</td>
<td>Package</td>
</tr>
<tr>
<td>Exp/Use By Date</td>
<td>Lot/Serial</td>
</tr>
<tr>
<td>Product Used?</td>
<td>No</td>
</tr>
<tr>
<td>Date Used?</td>
<td>Purchase Date</td>
</tr>
<tr>
<td>Amount Remaining</td>
<td>Date Discontinued</td>
</tr>
<tr>
<td>Country of Origin</td>
<td>Imported Product?</td>
</tr>
<tr>
<td>Retailer Name</td>
<td>Label Remarks</td>
</tr>
</tbody>
</table>

**Manufacturer/Distributor**

<table>
<thead>
<tr>
<th>FEI</th>
<th>Name &amp; Address</th>
<th>Home District</th>
<th>Firm Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>3006524310</td>
<td>Copomone Enterprises, LLC 7700 Congress Ave Ste 2201 Boca Raton FL 33487-1361</td>
<td>FLA-DO</td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

**Initial Evaluation / Initial Disposition**

<table>
<thead>
<tr>
<th>Initial Evaluation</th>
<th>FDA Action Indicated</th>
<th>Initial Disposition</th>
<th>Referred to Other FDA District</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Dispersion 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.

<table>
<thead>
<tr>
<th>Problem Keyword</th>
<th>Problem Keyword Details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>nausea, vomiting, diarrhea, burning/stinging eyes, disorientation, lightheadedness, tremors,</td>
</tr>
</tbody>
</table>

**Cosmetic**

<table>
<thead>
<tr>
<th>Cosmetic ID (h) (6)</th>
<th>DOB</th>
<th>Age</th>
<th>Gender</th>
<th>Race</th>
<th>Question Not Asked</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Female</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application Place</th>
<th>Salon/SPA</th>
<th>Reason for Use</th>
<th>Hair Preparations (Non-Coloring)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Application Site</th>
<th>Scalp</th>
<th>Other Products?</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directions Followed?</td>
<td>Yee</td>
<td>Product Duration</td>
<td></td>
</tr>
<tr>
<td>Frequency of Use</td>
<td>Other</td>
<td>Reaction Site</td>
<td>Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Use in Off-Label Manner?</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off-Label Manner Desc</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Warning Statement on Label?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warning Statements?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preexisting Conditions?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>Self-Medicated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Current Status</th>
<th>Improved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Diagnosis</td>
<td>Medical Treatment</td>
</tr>
</tbody>
</table>

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.
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 into the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

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

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

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

Sincerely yours,

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

Enclosure
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier
2. Age at Time of Event or Date of Birth:
   25 Years
(b) 6)
3. Sex
   □ Female □ Male
4. Weight
   125 lb
   or kg
   □ In confidence

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. [ ] Adverse Event
   [ ] Product Problem (e.g., defects/malfunctions)
   □ Product Use Error
   □ Problem with Different Manufacturer of Same Medicine
2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ Life-Threatening
   □ Congenital Anomaly/Birth Defect
   □ Hospitalization - Initial or prolonged
   □ Other serious (important medical events)
   □ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (mm/dd/yyyy)
   06/18/2014
4. Date of this Report (mm/dd/yyyy)
   06/22/2014
5. Describe Event, Problem or Product Use Error
   My saloon 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 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 ...

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: (mm/dd/yyyy)
   Manufacturer:

   #2 Name: 
   Strength: 
   Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name

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)
2. Health Professional? 3. Occupation
   □ Yes □ No
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: □

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event. 0000001
... 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 loopholes, it needs to be banned. Before someone gets permanent medical damage. Thank you.
### FACTS Interface

**FACTS Complaint #137637 (CAERS #177818)**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complaint Date</td>
<td>07/09/2014</td>
</tr>
<tr>
<td>Accomplishing District</td>
<td>LOS-DO</td>
</tr>
<tr>
<td>How Received</td>
<td>Telephone</td>
</tr>
<tr>
<td>Complainant Identification</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Address</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>City</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Zip</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Province</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>US</td>
</tr>
<tr>
<td>Mail Code</td>
<td></td>
</tr>
</tbody>
</table>

### Complaint / Injury

**Complaint Description**

Complainant reports having three "Brazilian Blowout" services (hair straightening treatments) done at a salon over 12 months (most recent service received on April 23, 2014). She alleges noticing her hair falling out and thinning in early May (clarifies that no balding/bald spots occurred). She initially believed her thinning hair was due to stress but now suspects this salon product is the cause because she learned of formaldehyde in the product through reports found on the internet. She reports discussing her concerns with the salon owner and states that the salon owner advised her that the product was reformulated and no longer contains formaldehyde. She also reports that when initially inquiring about the product, the salon owner advised her that she was the only one of 300 clients who received this service to complain about the product. Complainant called her Dermatologist the week of 05/30/2014 and was advised to take biotin to promote hair health. Dermatologist: Dr. Mark Liska, 37 Edgerton Drive, North Falmouth, MA 02555 (500-505-2550). Complainant requested information on any previous complaints about this product. Advised of FOIA and given FDA website information on FOIA requests. Complainant concerned about receiving closure for her specific complaint. She wishes to be advised of complaint outcome. She was provided with ACIL and ASTM private lab contact information should independent analysis of product be desired.

**Adverse Event Result**

Non-serious Injury/ Illness

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Event Date</td>
<td>05/2014</td>
</tr>
<tr>
<td>Notify EIO/EMOPS?</td>
<td>Yes</td>
</tr>
<tr>
<td>Notification Date</td>
<td>07/09/2014</td>
</tr>
<tr>
<td>Attended Health Professional?</td>
<td>No</td>
</tr>
<tr>
<td>Required Hospitalization?</td>
<td>No</td>
</tr>
<tr>
<td>Emergency Room/ Outpatient Visit?</td>
<td>No</td>
</tr>
<tr>
<td>Reported Complaint To?</td>
<td>Other</td>
</tr>
</tbody>
</table>

**Need Additional/ FDA Contact?**

Unknown

**Remarks**

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

### Complaint Symptoms

<table>
<thead>
<tr>
<th>Symptom Name</th>
<th>Duration</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Change in hair or nails, not listed</td>
<td>null null</td>
<td>Thinning hair, losing hair</td>
</tr>
</tbody>
</table>

### Health Care Professional

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

### Product and Labeling

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name</td>
<td>Brazilian Blowout</td>
</tr>
<tr>
<td>Product Name</td>
<td>Acai Professional Smoothing Solution</td>
</tr>
<tr>
<td>FDA Product Code</td>
<td>53ED03</td>
</tr>
<tr>
<td>Qty/Unit</td>
<td>34 Ounces</td>
</tr>
<tr>
<td>UPC Code</td>
<td>Unknown</td>
</tr>
<tr>
<td>Package</td>
<td>Bottle</td>
</tr>
<tr>
<td>Exp/Use By Date</td>
<td>Unknown</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------</td>
</tr>
<tr>
<td>Product Used?</td>
<td>Yes</td>
</tr>
<tr>
<td>Date Used?</td>
<td>05/2014</td>
</tr>
<tr>
<td>Amount Remaining</td>
<td>Unknown</td>
</tr>
<tr>
<td>Country of Origin</td>
<td></td>
</tr>
<tr>
<td>Retailer Name</td>
<td>Creative Cuts</td>
</tr>
</tbody>
</table>

**Manufacturer/Distributor**

<table>
<thead>
<tr>
<th>FEI</th>
<th>Name &amp; Address</th>
<th>Home District</th>
<th>Firm Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>3004432463</td>
<td>G.F. Distributors 34 Linnell Cir Billerica MA 01821-3901</td>
<td>NWE-DO</td>
<td>Distributor</td>
</tr>
<tr>
<td>3010034367</td>
<td>Trademark Cosmetics Inc 545 Columbia Ave Riverside CA 92507-2183</td>
<td>LOS-DO</td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

**Initial Evaluation / Initial Disposition**

<table>
<thead>
<tr>
<th>Initial Evaluation</th>
<th>FDA Action Indicated</th>
<th>Initial Disposition</th>
<th>Referred to Other FDA District</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposition Date</td>
<td>07/09/2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remarks Belgian blowout CEO Mark Brady (877-779-7006 x2150) confirmed manufacturer. Mr. Brady advised 2-3 similar complaints received over the last 6 years. Complainant gives permission to release personal information to company.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Problem Keyword**

<table>
<thead>
<tr>
<th>Other</th>
<th>Problem Keyword Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>thinning hair, losing hair</td>
<td></td>
</tr>
</tbody>
</table>

**Cosmetic**

<table>
<thead>
<tr>
<th>Cosmetic ID # (b) (G)</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>58</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>Race</th>
<th>Reason for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td></td>
<td>Hair Preparations (Non-Coloring)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application Site</th>
<th>Other Products?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salon/SPA</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Directions**

Three pumps is enough for one treatment

**Directions Followed?**

Yes

**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 glycol. When heated, this ingredient releases formaldehyde gas. Use in well-ventilated area and only as directed.

**Preexisting Conditions?**

No

**Current Status**

Unchanged

**Medical Diagnosis**

Medical Treatment

**Medical Treatment**

Dermatologist advised taking 1000 mcg Biotin (1 tablet/day)

**Remarks**

Complainant advised "3 pumps" from product bottle used per hair straightening service. Complainant purchased cervico 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.
1. **Patient Information**
   - Patient Identifier: (b)(6)
   - Sex: Female
   - Weight: 115 lb

2. **Adverse Event, Product Problem or Error**
   - Adverse Event: Yes
   - Product Problem (e.g., defects/malfunctions): Yes
   - Product Use Error: No
   - Problem with Different Manufacturer of Same Medicine: No
   - Outcomes Attributed to Adverse Event:
     - Death: 07/14/2014
     - Disability or Permanent Damage: 07/14/2014
     - Life-threatening: No
     - Other Serious (Important Medical Events): No
     - Hospitilization - Initial or Prolonged: No
     - Other: No
   - Other Relevant History, Including Preexisting Medical Conditions:
     - Race: White
     - For additional information see B7 below.

3. **Product Availability**
   - Product Available for Evaluation: Yes

4. **Suspect Product(s)**
   - Manufacturer: (b)(6)
   - Name: Keratin Treatment
   - Strength: 07/14/2014

5. **Other Concomitant Medical Products**
   - Product names and therapy dates (exclude treatment of event)

6. **Reporter**
   - Name: (b)(6)
   - Address: (b)(6)
   - City: (b)(6)
   - State: (b)(6)
   - ZIP: (b)(6)
   - Phone #: (b)(6)
   - E-mail: (b)(6)

7. **Other Concomitant Medical Products**
   - Other:

8. **Form FDA 3500 (1/09)**
   - Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
... mention my burning eyes, the rash I get across my neck... and many other awful complaints. I am afraid this stuff is going to seriously injure us. It is not right. This has to be stopped. Please advise. Thanks, Stephanie
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Medical Conditions: Hypothyroid

Allergies: Clindamycin

Important Information:

RX Meds: Levothyroxine 75mcg

OTC Meds: Multivitamin, omega 3,4,9, biotin
### A. PATIENT INFORMATION

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

In confidence:

### B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event
2. ☐ Product Problem (e.g., defects/malfunctions)
3. ☐ Product Use Error
4. ☐ Problem With Different Manufacturer of Same Medicine

Outcomes Attributed to Adverse Event

- ☑ 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)

### C. PRODUCT AVAILABLE

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:

### E. SUSPECT MEDICAL DEVICE

1. Brand Name

### F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

### G. REPORTER

Name: (b) (6)
Address:
City: 
State: 
ZIP: 
Phone #: 
E-mail: 

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

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

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

FORM FDA 3500 (1/09)
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 asked how it bad it was. I 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
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,

[Signature]

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

Enclosure
MedWatch
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (b) (6)
   2. Age at Time of Event or Date of Birth:
      [51 Years]
   3. Sex
      [Female]
   4. Weight
      [145 lb]

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
   [ ] 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
Return product to manufacturer on:

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   1A. Name: [Brazillian Blowout (Keratin)]
   1B. Strength: not known by this consumer
   1C. Manufacturer: [Brazillian Blowout]

2. Name:
   [ ] Strength:
   [ ] Manufacturer:

2. Dose or Amount
   Frequency
   Route
   
2. Dates of Use (if unknown, give duration) (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 #
   7. Expiration Date
      #1
      #2

8. If Implanted, Give Date (mm/dd/yyyy)
9. If Explanted, Give Date (mm/dd/yyyy)

10. Is this a single-use device that was Reprocessed and Reused on a Patient?
    [ ] Yes
    [ ] No

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

E. SUSPECT MEDICAL DEVICE

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)

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:
   [ ]

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
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 those types of treatments are permitted by law (which I don't think they should be), can you require salons to post something about the products, and at least give the customers a verbal warning that they might be endangering their health? Thank you.
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race: White
Medical Conditions: none known
Allergies: none known
Important Information: n/a
RX Meds: n/a
OTC Meds: n/a
August 26, 2014

To Whom It May Concern:

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

The FDA Safety Information and Adverse Event Reporting Program

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

Page 1 of 2

**A. PATIENT INFORMATION**

1. Patient Identifier:
   - [ ] Confidential
   - [ ] Insider (b) (6)

2. Age at Time of Event, or Date of Birth:
   - [ ] Female (b) (6)
   - [ ] Male
   - [ ] Other

3. Sex:
   - [ ] Female
   - [ ] Male

4. Weight:
   - [ ] 150 lbs
   - [ ] 150 lb
   - [ ] Other

5. Height:
   - [ ] 6 ft
   - [ ] 6 ft
   - [ ] Other

6. Race:
   - [ ] White
   - [ ] Black
   - [ ] Hispanic
   - [ ] Other

7. Ethnicity:
   - [ ] Caucasian
   - [ ] African American
   - [ ] Hispanic
   - [ ] Other

8. Date of Birth:
   - [ ] 01/01/2014
   - [ ] 02/02/2014
   - [ ] Other

9. Place of Birth:
   - [ ] Hospital
   - [ ] Home
   - [ ] Other

10. Country of Birth:
    - [ ] United States
    - [ ] Foreign

11. State of Residence:
    - [ ] Illinois
    - [ ] Other

12. City of Residence:
    - [ ] Chicago
    - [ ] Other

13. ZIP Code:
    - [ ] 60657
    - [ ] Other

14. Phone Number:
    - [ ] Home
    - [ ] Work
    - [ ] Cell

15. Email Address:
    - [ ] Work
    - [ ] Personal

16. Relationship to Patient:
    - [ ] Patient
    - [ ] Family Member
    - [ ] Other

17. Date of Event:
    - [ ] 03/15/2014
    - [ ] 04/04/2014
    - [ ] Other

18. Date of this Report:
    - [ ] 05/05/2014
    - [ ] 06/06/2014
    - [ ] Other

19. Date of Latest Follow-Up:
    - [ ] 07/07/2014
    - [ ] 08/08/2014
    - [ ] Other

20. Reason for Follow-Up:
    - [ ] Further Treatment
    - [ ] Resolution of Event
    - [ ] Other

21. Date of Death:
    - [ ] 09/09/2014
    - [ ] 10/10/2014
    - [ ] Other

22. Cause of Death:
    - [ ] Natural
    - [ ] Non-Natural
    - [ ] Other

23. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.):
    - [ ] Yes
    - [ ] No

24. Relevant Tests/Laboratory Data, Including Dates:
    - [ ] Yes
    - [ ] No

25. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.):
    - [ ] Yes
    - [ ] No

26. Relevant Tests/Laboratory Data, Including Dates:
    - [ ] Yes
    - [ ] No

**B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR**

Check all that apply:

1. [ ] Adverse Event
2. [ ] Product Problem (e.g., defect, malfunction)
3. [ ] Product Use Error
4. [ ] Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
   - [ ] Death
   - [ ] Serious or permanent damage
   - [ ] Hospitalization
   - [ ] Other

3. Date of Event:
   - [ ] 03/15/2014
   - [ ] 04/04/2014
   - [ ] Other

4. Date of this Report:
   - [ ] 05/05/2014
   - [ ] 06/06/2014
   - [ ] Other

5. Description of Event, Problem or Product Use Error:
   - [ ] Yes
   - [ ] No

6. Event Aborted After Use:
   - [ ] Yes
   - [ ] No

7. Date of Use:
   - [ ] 03/15/2014
   - [ ] 04/04/2014
   - [ ] Other

8. Date of Event:
   - [ ] 03/15/2014
   - [ ] 04/04/2014
   - [ ] Other

9. Date of Follow-Up:
   - [ ] 05/05/2014
   - [ ] 06/06/2014
   - [ ] Other

10. Date of Death:
    - [ ] 07/07/2014
    - [ ] 08/08/2014
    - [ ] Other

11. Cause of Death:
    - [ ] Natural
    - [ ] Non-Natural
    - [ ] Other

**C. PRODUCT AVAILABILITY**

Product available for purchase? (Check one)

- [ ] Yes
- [ ] No
- [ ] Returned to manufacturer (mm/dd/yyyy):

**D. SUSPECT PRODUCT(S)**

1. Name, Strength, Manufacturer (from package label):
   - [ ] Brazilian Blow Out

2. Description:
   - [ ] Yes
   - [ ] No

3. Date of Use:
   - [ ] 03/15/2014
   - [ ] 04/04/2014
   - [ ] Other

4. Date of Event:
   - [ ] 03/15/2014
   - [ ] 04/04/2014
   - [ ] Other

5. Date of Follow-Up:
   - [ ] 05/05/2014
   - [ ] 06/06/2014
   - [ ] Other

6. Date of Death:
   - [ ] 07/07/2014
   - [ ] 08/08/2014
   - [ ] Other

7. Cause of Death:
   - [ ] Natural
   - [ ] Non-Natural
   - [ ] Other

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name:
2. Common Device Name:
3. Manufacturer Name, City and State:
4. Model #:
5. Lot #:
6. Operator of Device:
   - [ ] Health Professional
   - [ ] In Vitro Diagnostics
   - [ ] Other

7. If Implanted, Give Date (mm/dd/yyyy):
8. If Explanted, Give Date (mm/dd/yyyy):
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:
   - [ ] Yes
   - [ ] No

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:

**FORM FDA 3500 (10/05)** Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
September 15, 2014

Yehia Company
1455 East 53rd
Chicago, Illinois 60018

To Whom It May Concern:

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

FACTS Complaint #137131 (CAERS #179044)

Complaint Date: 05/27/2014
Accomplishing District: LOS-DO
How Received: Telephone

Local Government: Archive

Complaint Identification

Name: (b) (6)
Address: (b) (6)
City: (b) (6)
State: (b) (6)
Zip: (b) (6)
Province: 
Country: US
Mail Code: 

Work Phone: 
Home Phone: (b) (6)
Source POC Name: 
Source Phone: 

Complaint / Injury

Complaint Description:
Complainant is an independent contractor employed by a beauty salon. Reports second hand reactions to the product Brazilian Blowout being used at the salon. Reactions described as nose drainage, racing 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 Result: None
Adverse Event Date: 
Notify EIO/EMOPS?: Yes
Notification Date: 05/27/2014
Required Health Professional?: No
Required Hospitalization?: No
Emergency Room/Outpatient Visit?: No
Reported Complaint To?: 
Need Additional/FDA Contact?: 

Complaint Symptoms

Symptom Name: Change in heart rate, pulse; palpitations, fibrillation, Shortness of breath on exertion, NEC - Identify in Remarks
Duration: null null
Remarks: racing, 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
UPC Code: Package
Exp/Use By Date: Lot/Serial 717713H
Product Used?: No
Purchase Date: 
Date Used?: 
Amount Consumed/Used: 
Date Discontinued: 
Country of Origin: Brazil
Imported Product?: No
Retailer Name: Living Art
Label Remarks: 

0000001
## Manufacturer/Distributor

<table>
<thead>
<tr>
<th>FEI</th>
<th>Name &amp; Address</th>
<th>Home District</th>
<th>Firm Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>3008593985</td>
<td>Brazilian Blowout 6855 Tujunga Ave North Hollywood CA 91605-6312</td>
<td>LOS-DO</td>
<td>Distributor</td>
</tr>
<tr>
<td>3007129690</td>
<td>Cadiveu Cosmeticos Martim De 3a 75 Sao Paulo null null</td>
<td></td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

## Initial Evaluation / Initial Disposition

<table>
<thead>
<tr>
<th>Initial Evaluation</th>
<th>FDA Action Indicated</th>
<th>Initial Disposition</th>
<th>Referred to Other FDA District</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposition Date</td>
<td>06/03/2014</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Remarks

- No additional product information provided.

### Problem Keyword Details

- **Problem Keyword**: drainage, racing heartbeat, breathlessness

### Cosmetic

<table>
<thead>
<tr>
<th>Cosmetic ID #(h) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOB</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Race</td>
</tr>
<tr>
<td>Application Place</td>
</tr>
<tr>
<td>Reason for Use</td>
</tr>
<tr>
<td>Application Site</td>
</tr>
<tr>
<td>Other Products?</td>
</tr>
</tbody>
</table>

### Directions

- Directions Followed?
- Product Duration
- Frequency of Use
- Reaction Site
- Other
- Product Use in Off-Label Manner?
- Off-Label Manner Desc

### Warning Statement on Label?

-Warning Statements?*

### Preexisting Conditions?

- Treatment

### Current Status

- Medical Diagnosis
- Medical Treatment

### Remarks

- second hand exposure

### Adverse Events

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

[Close]
October 09, 2014

Cadiveu Cosmeticos
Martim De Sa 75
Sao Paulo,
Brazil

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 179044.

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

Sincerely yours,

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

Enclosure
# MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

## A. PATIENT INFORMATION

1. Patient Identifier
   - A. Number: [Redacted]
   - B. Sex: Female
   - Date of Birth: 29 Years

2. Date of Event (mm/dd/yyyy): 08/15/2014
3. Date of This Report (mm/dd/yyyy): 09/10/2014

## B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

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

2. Outcomes Attributed to Adverse Event
   - Death
   - 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)

## C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
   - Yes
   - No
   - Returned to Manufacturer on: [Redacted]

## D. SUSPECT PRODUCT(S)

1. Name: [Redacted]
   - Manufacturer: [Redacted]

2. Name: [Redacted]
   - Strength: [Redacted]
   - Manufacturer: [Redacted]

## E. SUSPECT MEDICAL DEVICE

1. Brand Name: CTU
2. Common Device Name: [Redacted]
3. Manufacturer Name, City and State: [Redacted]

## F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

## G. REPORTER

(See confidentiality section on back)

1. Name and Address
   - Name: Florence Millon
   - Address: [Redacted]
2. Phone #: [Redacted]
3. E-mail: [Redacted]
4. Also Reported to:
   - [Redacted]
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: [Redacted]
On August 18, 2014 I had a basaloid 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.
8.6. Relevant Tests/Laboratory Data, Including Dates (continued)

Biopsy of nodule: verrucous dermatitis
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatorenal dysfunction, etc.) (continued)

Race: White
Medical Conditions:

Allergies: NCEA

Important Information:

OTC Meds: Hydrocortisone, Benadryl
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier
   (b) (6)

2. Age at Time of Event or Date of Birth:
   (b) (6)

3. Sex
   [Female]
   [Male]

4. Weight
   [lb]
   [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:
   [ ] 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 (Device)

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

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

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
   See page 4 for complete text.

C. PRODUCT INFORMATION

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   #1 Name: [Necrotic treatment Rejuvenol]
   Strength: [not told]
   Manufacturer: [Rejuvenol]

   #2 Name:
   Strength:
   Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

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

6. Catalog #

7. Expiration Date (mm/dd/yyyy)

8. Lot #

9. Other #

10. If Implantation, Give Date (mm/dd/yyyy)

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

12. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   [ ] Yes
   [ ] No

13. If Yes to Item No. 12, 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: [BP] 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: [ ]

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
B.5. Describe Event or Problem (continued)

I can't stop coughing and it's hard to breathe after this keratin treatment (rejuvenol) at the salon synergy on 981 W Wales road, PA 19454
February 05, 2015

Rejuvenol
415 Bayview Ave
Amityville, New York 11701

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 # 181880.

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

Sincerely yours,

Lyle Canida, Pharm.D., M.S.
LCRD, 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
### A. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>Patient Identifier</th>
<th>Age at Time of Event</th>
<th>Date of Birth</th>
<th>Sex</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (c)</td>
<td>(b) (c)</td>
<td>(b) (c)</td>
<td>(b) (c)</td>
<td>148 (b)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>□ Female</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>□ Male</td>
<td></td>
</tr>
</tbody>
</table>

### B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

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

2. Outcomes Attributed to Adverse Event
   - [ ] Death: (mm/dd/yyyy)
   - [ ] Disability or Permanent Damage
   - [ ] Life-threatening
   - [ ] Congenital Anomaly/ Birth Defect
   - [ ] Hospitalization - initial or prolonged
   - [ ] Other Serious (Important Medical Events)
   - [ ] Requires 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. Event Abated After Use
   - [ ] Yes
   - [ ] No
   - [ ] Doesn't Apply

6. Diagnosis or Reason for Use (Indication)
   - #1 This product was applied by a professional stylist or salon

7. Lot #
   - #1
   - #2

8. Expiration Date
   - #1
   - #2

### 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 Name: 
   - Strength: 
   - Manufacturer:

### E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

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

4. **Model #**
5. **Serial #**
6. **Catalog #**
7. **Expiration Date (mm/dd/yyyy):**
8. **Operator of Device**
   - [ ] Health Professional
   - [ ] Law User/Patient
   - [ ] Other:

9. **If Implanted, Give Date (mm/dd/yyyy):**
10. **If Implanted, Give Date (mm/dd/yyyy):**

### 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**
   - [ ] Yes
   - [ ] No
   - [ ] Returned to Manufacturer on: (mm/dd/yyyy)

2. **Health Professional?**
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)

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 experiencing 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 it... 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 737-729-2699. Sincerely, Jennifer Thayer.
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

No tests taken at this point
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Medical History
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)

DRX Meds: None

OTC Meds: Vitamin C, Magnesium Glycinate, Advaclear, UltraInflamX plus 360 - all of these items are mainly used to help with this issue.
January 29, 2015

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

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered into 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/foia/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 # 182030.

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.
LCR, 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
B.5. Describe Event or Problem (continued)

I received a brazilian hair straightening treatment on 2/11/15 in which Original Keratin product was used. My eyes and nose burned significantly while it was being applied. My scalp burned a little. That evening when I went to bed my eyes and nose started burning again keeping me awake. The skin around the hairline of my face was red. I washed my hair several times. It is now 2/13/15 and my skin is still somewhat red. I still get a headache everyday. It feels like a sinus headache. My eyes are burning but not sure if it’s from the hair straightening.
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race: White
Medical Conditions: Low thyroid
Allergies: none
Important Information: None
RX Meds: 75 mcg levothyroxine daily
OTC Meds: Green Vibrance, Vitamin D, Calcium, Fish oil
March 09, 2015

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

To Whom It May Concern:

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

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

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
      ☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
      ☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
      ☐ Required Intervention to Prevent Permanent Impairment/Defamage (Devices)
   3. Date of Event (mm/dd/yyyy) 03/29/2015
   4. Date of this Report (mm/dd/yyyy) 03/31/2015

C. PRODUCT AVAILABILITY
   (Do not send product to FDA)
   ☐ Yes ☐ No ☐ Returned to Manufacturer on:

D. SUSPECT PRODUCT(S)
   1. Name: ____________________ Strength: ____________________
      Manufacturer: ____________________
   2. Name: ____________________ Strength: ____________________
      Manufacturer: ____________________

See additional page(s) for complete text.

E. SUSPECT MEDICAL DEVICE
   1. Brand Name ____________________
   2. Common Device Name ____________________
   3. Manufacturer Name, City and State ____________________ APR - 1 2015
   4. Model #: ____________________ Lot #: ____________________
   5. Operator of Device
      ☐ Health Professional
      ☐ Lay User/Patient
      ☐ 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. If Yes to Item No. 5, Enter Name and Address of Reprocessor
      ☐ Yes ☐ No
   9. If this a Single-use Device that was Reprocessed and Reused on a Patient?
      ☐ Yes ☐ No

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: ____________________ Address: ____________________
      City: Tampa State: FL ZIP: 33629
      Phone #: ____________________ E-mail: ____________________
   2. Health Professional? ☐ Yes ☐ No
   3. Occupation ☐ Health Professional ☐ Other:
      ☐ Lay User/Patient
      ☐ Other:
   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: ☐

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

000001
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 Pre-existing 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 into 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/foia/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.
LCNR, 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

A. PATIENT INFORMATION
1. Patient Identifier
   (b) (6)
   In confidence
2. Age at Time of Event or
   Date of Birth:
   59 Years
3. Sex
   ✔ Female
   or
   □ 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 Used 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)
   04/21/2015
4. Date of this Report (mm/dd/yyyy)
   04/24/2015

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:

See additional page(s) for complete text.

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 natural
ermitec
   #2

5. Event Substituted After Use
   Stopped or Dose Reduced?
   #1 Yes
   □ No
   □ Doesn’t Apply
   #2

6. Event, Reappeared After
   Discontinuation?
   #1 Yes
   □ No
   □ Doesn’t Apply
   #2

7. Lot #
   #1
   #2

8. 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 #

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

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Implanted, 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:

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

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

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

0000001
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 5785 Center Parkway, Ste 310B, 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, cataract, 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)
### A. PATIENT INFORMATION
1. Patient Identifier
2. Age at Time of Event or Date of Birth: 44 Years
3. Sex: Female
4. Weight: 75 lbs

### B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. **Adverse Event**: Yes
   - **Product Problem** (e.g., defects/malfunctions): Yes
   - **Product Use Error**: No
2. **Outcomes Attributed to Adverse Event**
   - Death: Yes
   - Disability or Permanent Damage: Yes
   - Life-threatening: No
   - Congenital Anomaly/Birth Defect: No
   - Hospitalization - Initial or prolonged: No
   - Other Serious (Important Medical Events): No
3. **Date of Event** (mm/dd/yyyy): 06/16/2015
4. **Date of this Report** (mm/dd/yyyy): 06/23/2015

### C. PRODUCT AVAILABILITY
Product Available for Evaluation?: Yes

### D. SUSPECT PRODUCT(S)
1. **Name**: [Product Name]
   - **Strength**: [Strength]
   - **Manufacturer**: [Manufacturer]
2. **Name**: [Product Name 2]
   - **Strength**: [Strength]
   - **Manufacturer**: [Manufacturer]

### E. SUSPECT MEDICAL DEVICE
1. **Brand Name**: [Brand Name]
2. **Common Device Name**: [Common Device Name]
3. **Manufacturer Name, City and State**: [Manufacturer Name, City and State]
4. **Model #**: [Model Number]
5. **Lot #**: [Lot Number]
6. **Operator of Device**
   - [Operator Details]
7. **Catalog #**: [Catalog Number]
8. **Expiry Date** (mm/dd/yyyy): [Expiry Date]
9. **Serial #**: [Serial Number]
10. **Other #:**: [Other Number]

### 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**
2. **Health Professional?**: Yes
3. **Occupation**: [Occupation]
4. **Also Reported to**:
   - [Reported to Details]

### FDA USE ONLY
Triage unit sequence #: 602433

### Additional Notes
See additional page(s) for complete text.
8.5. 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 claims by beauty salon for using formaldehyde free products I had abnormal eye and breast 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 I had severe peri-orbital 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.

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

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

Race: White

Medical Conditions: Hypothyroidism

Allergies: Latex

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

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

RX Meds: Levothyroxine, 75 mcg daily

OTC Meds: Multivitamin 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 into 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.  
LCVR, 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

A. PATIENT INFORMATION
1. Patient Identifier: [Redacted]
2. Age at Time of Event or Date of Birth: [Redacted]
3. Sex: Female
4. Weight: 135 lbs

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. Date of Event (mm/dd/yyyy): 07/08/2015
4. Date of this Report (mm/dd/yyyy): 07/27/2015
5. Event Stopped After Use Stopped or Dose Reduced?
   - Yes
   - No
   - Doesn't Apply

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
- Yes
- No

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   - Name: [Redacted]
   - Strength: [Redacted]
   - Manufacturer: [Redacted]
2. Name: [Redacted]
   - Strength: [Redacted]
   - Manufacturer: [Redacted]

E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Lot #
6. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other
7. If Implanted, Give Date (mm/dd/yyyy)
8. If Implanted, Give Date (mm/dd/yyyy)
9. If Yes to Item No. 8, Enter Name and Address of Implanter/Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
See additional page(s) for complete text.

G. REPORTER (See confidentiality section on back)
1. Name and Address
2. City/State
3. Phone #
4. Also Reported to:
   - Manufacturer
   - User Facility/Institution

See additional page(s) for complete text.
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 Primo Salon at Crabtree Valley Mall in Raleigh NC while visiting family and friends on vacation. Their telephone number is 919-232-8652. 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: No

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 into 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

A. PATIENT INFORMATION
1. Patient Identifier
2. Age at Time of Event, or Date of Birth:
3. Sex [ ] Female [ ] Male
4. Weight [ ] lb [ ] 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 of Permanent Damage
   [ ] Life-threatening [mm/dd/yyyy]
   [ ] 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]

5. Describe Event, Problem or Product Use Error
   Reaction to product. Product is distributed by OH hair in FL

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) (mm/dd/yyyy) or (best estimate)
   #1
   #2

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

5. Event Abated After Use
   [ ] Yes [ ] No
   [ ] Doesn’t Apply

6. Event Reappeared After Reintroduction?
   [ ] Yes [ ] No
   [ ] Doesn’t Apply

7. Lot #
   #1
   #2

8. Expiration Date
   #1
   #2

E. SUSPECT MEDICAL DEVICE
1. Brand Name

9. Common Device Name

3. Manufacturer Name, City and State

4. Model #
5. Operator of Device
   [ ] Health Professional
   [ ] 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

FORM FDA 3500 (10/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
February 04, 2016

Peter Coppola 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.

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 # 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.
LCOR, 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 into 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/foia/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 # 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,

[Signature]

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**

**A. PATIENT INFORMATION**

1. **Patient Identifier**
   - (ID)
   - **Year(s):**
   - **Month(s):**
   - **Day(s):**

2. **Sex**
   - [ ] Male
   - [ ] Female

3. **Weight**
   - [ ] lb
   - [ ] kg

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

**B. ADVERSE EVENT, PRODUCT PROBLEM**

1. **Check all that apply**
   - [ ] Adverse Event
   - [ ] Product Problem (e.g., defects/malfunctions)
   - [ ] Product Use Error

2. **Outcome Attributed to Adverse Event (Check all that apply)**
   - [ ] Death Include date (dd-mm-yyyy)
   - [ ] Life-Threatening
   - [ ] Hospitalization - initial or prolonged
   - [ ] Other Serious (important medical events)
   - [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event (dd-mm-yyyy)**
   - 11-Apr-2015

4. **Date of This Report (dd-mm-yyyy)**
   - 05-May-2016

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

6. **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-mm-yyyy)

**D. SUSPECT PRODUCTS**

1. **Name, Manufacturer/Compounder, Strength (from product label)**
   - #1 - Keratin Cure chocolate max VI
     - #1 - NDC # or Unique ID
     - #2 - Lot #
   - #2 - Keratin Cure
     - #1 - Lot #
     - #2 - NDC # or Unique ID

2. **Name and Strength**
   - #1 - NDC # or Unique ID
   - #1 - Lot #

3. **Dose or Amount**
   - [ ] Frequency
   - [ ] Route

4. **Dates of Use (From/To for each) (If unknown, box duration or at best estimate) (dd-mm-yyyy)**
   - #1 - 11-Apr-2015
   - #2

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

6. **Is the Product Compounded?**
   - #1
   - #2

7. **Is the Product Over-the-Counter?**
   - #1
   - #2

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

9. **If Implanted, Give Date (dd-mm-yyyy)**

10. **If Explanted, Give Date (dd-mm-yyyy)**

**E. SUSPECT MEDICAL DEVICE**

1. **Brand Name**

2. **Common Device Name**

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

4. **Model #**

5. **Lot #**

6. **Operator of Device**
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] Other

7. **Catalog #**

8. **Expiration Date (dd-mm-yyyy)**

9. **Serial #**
   - Unique Identifier (UDI) #

10. **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)

1. **Name and Address**
   - Last Name
   - First Name
   - Address

2. **City:**
   - State/Province/Region:

3. **Country:**
   - ZIP/Postal Code:

4. **Phone #:**
   - E-mail:

5. **Also Reported to:**
   - [ ] Manufacturer
   - [ ] Complier
   - [ ] User Facility
   - [ ] Distributor/Importer

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

1. **Name and Address**
   - Last Name
   - First Name
   - Address

2. **City:**
   - State/Province/Region:

3. **Country:**
   - ZIP/Postal Code:

4. **Phone #:**
   - E-mail:

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

**NOTE:** Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
2.5. 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.

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

2.7. 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)
### 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
   - [ ] Hospitalization - initial or prolonged
   - [ ] Other Serious (important medical events)
   - [ ] Life-threatening
   - [ ] Disability or Permanent Damage
   - [ ] Congenital Anomaly/Birth Defects
   - [ ] Required intervention to prevent permanent impairment/damage (Device)

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

4. **Date of this Report (dd-mm-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 Proximate Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)**
   - See additional page(s) for complete text.

### Product Availability

2. **Product Available for Evaluation? (Do not send product to FDA)**
   - [ ] Yes
   - [ ] No
   - [ ] Returned to Manufacturer on: __________

### Suspect Products

1. **Name, Manufacturer/Componaker, Strength (from product label)**
   - **Keratin cure chocolate max vi**
     - **NDC # or Unique ID**

2. **Name and Strength**
   - **Keratin Cure**

3. **Name and Strength**
   - **NDC # or Unique ID**

4. **Manufacturor/Componaker**
   - **Keratin Cure**

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

1. **Name and Address**
   - City: ______________ State/Province/Region: ______________ Country: ______________
   - ZIP/Postal Code: ______________

2. **Phone #:** ______________

3. **Also reported to:**
   - [ ] Dr. Manufacturer Componaker
   - [ ] User Facility
   - [ ] Distributor/Importer

4. **You do NOT want your identity disclosed to the manufacturer, please mark this box:** ______________
2.5. Describe Event or Problem  (continued)
I ordered a keratin hair treatment from keratinure.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.

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

2.7. 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:

2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)  (continued)
July 21, 2016

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

Re: CAERS# 196079

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

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

Regards,
Mourad Ramoul
C.E.O

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 into the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 196079.

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

Sincerely yours,

[Signature]

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

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)[b]
   - Age: 
     - Year(s) 
     - Month(s) 
     - Day(s) 
   - Sex: 
     - Female 
     - Male
   - or Date of Birth (e.g., 08 Feb 1925) 
2. Ethnicity (Check single best answer)
   - Hispanic/Latino
   - Not Hispanic/Latino
3. Race (Check all that apply)
   - Asian
   - American Indian or Alaskan Native
   - Black or African American
   - White
   - Other Races
4. Weight
   - lb
   - kg

B. ADVERSE EVENT, PRODUCT PROBLEM
1. Check all that apply
   - Adverse Event
   - Product Problem (e.g., defects, malfunctions)
   - Product Use Error
2. Outcome Attributed to Adverse Event (Check all that apply)
   - Death
   - Life-threatening
   - Hospitalization - initial or prolonged
   - Other Serious (important Medical Events) migraine, burn at all passage
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
   See additional page(s) for complete text.
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, hyper/hypertension, 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)
   - Name and Strength
   - Manufacturer/Compounder

   #1 - Name and Strength
   - EBG

   #2 - Name and Strength
   - NDC # or Unique ID

   #2 - Manufacturer/Compounder

   #2 - Lot #

   #2 - Lot #

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

C. REPORTER (See confidentiality section on back)

1. Name and Address
   - Last Name: (b) (6)
   - First Name: (b)
   - Address: 105 south 2nd street
   - City: (b) (6)
   - State/Province/Region: (b) (6)
   - Country: US
   - Zip/Postal Code: (b) (6)

   - Phone # (b) (6)

   - E-mail (b) (6)

2. Health Professional?
   - Yes
   - No

3. Occupation

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

5. If you do not want your identity disclosed to the manufacturer, please mark this box: 
   - Yes
   - No
B.5. Describe Event or Problem (continued)

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

---

**A. PATIENT INFORMATION**

1. Patient Identifier System:
   - [ ] None
   - [ ] Name
   - [ ] Social Security Number
   - [ ] Other
   - [ ] Date of Birth (e.g., 08 Feb 1925)

2. Age:
   - [ ] Year(s)
   - [ ] Month(s)
   - [ ] Day(s)
   - [ ] Week(s)
   - [ ] Day(s)

3. Sex:
   - [ ] Female
   - [ ] Male

4. Weight:
   - [ ] lb
   - [ ] kg

---

**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

---

**C. PRODUCT AVAILABILITY**

2. Product Available for Evaluation? (Do not send product to FDA):
   - [ ] Yes
   - [ ] No
   - [ ] Returned to Manufacturer on:

---

**D. SUSPECT PRODUCTS**

1. Name, Manufacturer/Componder, Strength (from product label):
   - [ ] NDC # or Unique ID
   - [ ] Lot #

   - [ ] Name and Strength
   - [ ] Manufacturer/Componder

   - [ ] Name and Strength
   - [ ] NDC # or Unique ID
   - [ ] Manufacturer/Componder

---

**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

Product names and therapy dates (Exclude treatment of event)

---

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

1. Name and Address:
   - [ ] Name
   - [ ] Address
   - [ ] City
   - [ ] State/Province/Region
   - [ ] Country
   - [ ] ZIP/Postal Code

---

**G. FDA USE ONLY**

- [ ] Yes
- [ ] No
- [ ] Does not apply

---

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

A. PATIENT INFORMATION

1. Patient Identifier

2. Age

3. Sex

4. Weight

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply

2. Outcome Attributed to Adverse Event

3. Date of Event

4. Date of this Report

5. Describe Event, Problem or Product Use Error

6. Relevant Tests/Laboratory Data, including Dates

7. Other Relevant History, including Pre-existing Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, surgery problems, etc.)

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation?

D. SUSPECT PRODUCTS

2. Name, Manufacturer/Componence, Strength (from product label)

3. Brazilian Blowout Acai Extract

#1 - NDC # or Unique ID

#2 - NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Catalog #

6. Expiration Date

7. Unique Identifier (UDI) #

8. If Implantable, Give Date

9. If Explanted, Give Date

10. Is this a single-use device that was reprocessed and reused on a patient?

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates

C. REPORTER

1. Name and Address

2. Health Professional?

3. Occupation

4. Also Reported to:

5. Please mark this box if you do not want your identity disclosed to the manufacturer.
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: Sulfas drugs
Important Information: None

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

BY Meds: Ciclosporin 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

Note: For date prompts of 'mm-dd-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 (e.g. Social Security Number)
2. Age [Year(s)] [Month(s)] [Day(s)]
Yes [Female] No [Male] [Weight] [kg]

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

5. a. Ethnicity (Check at least one answer)
[Hispanic/Latino] [Asian] [American Indian or Alaskan Native] [Black or African American] [White]
[b. Race (Check at least one answer)]

Not Hispanic/Latino Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM
1. Check all that apply
Yes [Adverse Event] No [Product Problem (e.g., defects/malfunctions)]

No [Product Use Error] Problem with Different Manufacturer of Same Medicine

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

[Death] [Injury] [Disability or Permanent Damage]

[Hospitalization - Initial or Prolonged] [Congenital Anomaly/Birth Defect]

[Other (severe important medical event)] [Required Intervention to Prevent Permanent Impairment/Damage (Devices)]

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

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

18-Apr-2016

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.

C. PRODUCT AVAILABILITY
2. Product Available for Evaluation? (Do not send product to FDA)

Yes [No] [Returned to Manufacturer on (dd-mm-yyyy)]

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

Brazilian Blowout Acai Professional

#1 - Name and Strength

Brazilian Blowout

#2 - Name and Strength

Brazilian Blowout

1. NDC # or Unique ID

2. Lot #

E. SUSPECT MEDICAL DEVICE
1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

4. Model #

Lot #

5. Catalog #

Expiry Date (dd-mm-yyyy)

6. Serial #

Unique Identifier (UDI) #

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

C. REPORTER
1. Name and Address

(b) (6)

2. Health Professional? 3. Occupation

Yes [No]

4. Also Reported to:

[Manufacturer/Compounder] [User Facility]

Distributor/Importer

6. If you do not want your identity disclosed to the manufacturer, please mark this box:

Form FDA 2550 (4/16)

[PRINT IN INK OR USE BLACK INK]

PLEASE TYPE OR USE BLACK INK
3.5. 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.

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

None

3.7. 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: Ciclopizone 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
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

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

A. PATIENT INFORMATION
1. Patient Identifier
   A. Name/ID (Last Name) (b) (6)
   B. Social Security Number
2. Age
   A. Year(s) (b) (6)
   B. Month(s)
   C. Day(s)
3. Sex
   ☐ Male
   ☐ Female

4. Weight
   A. lb
   B. kg
5. Ethnicity
   ☐ Hispanic/Latino
   ☐ Asian
   ☐ American Indian or Alaskan Native
   ☐ Black or African American
   ☐ White
   ☐ Not Hispanic/Latino
   ☐ Native Hawaiian or Other Pacific Islander
6. Race
   ☐ Asian
   ☐ American Indian or Alaskan Native
   ☐ Black or African American
   ☐ White
   ☐ Not Hispanic/Latino
   ☐ 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
   ☐ Death
   ☐ 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)
2. Outcome Attributed to Adverse Event
   ☑ Yes
   ☐ No

3. Date of Event (dd-mm-yyyy)
   20-Jun-2016

4. Date of this Report (dd-mm-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, shark, and abdominal 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:

D. SUSPECT PRODUCTS
1. Name, Manufacturer/Compounder, Strength (from product label)
   #1 - Manufacturer/Compounder
   GIB LLC
   #1 - Lot #
   9847150
   #2 - Name and Strength
   1 oz 350 ml
   ☑ Yes
   ☐ No

2. Product Problem
   ☑ Yes
   ☐ No

E. SUSPECT MEDICAL DEVICE
1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State
   Cigarettes
   Detroit, MI

4. Model #

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

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)
   Address (b) (6)

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

   Country
   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
   ☐ Other:

5. If you do not want your identity disclosed to the manufacturer, please mark this box:
   ☑ Yes
   ☐ No

FORM FDA 3500 (4/14) - Submission of a report does not constitute an admission that medical device was the product involved or contributed to the event.
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/canal dysfunction, etc.) (continued)

Medical Conditions: Mild asthma

Allergies: Sulfa drugs bactruim

Important Information:

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

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

OTC Meds:
### A. PATIENT INFORMATION

1. **Patient Identifier**
   - [ ] Name (Patient's full name)
   - [ ] Social Security Number

2. **Age**
   - [ ] Years
   - [ ] Month(s)
   - [ ] Day(s)
   - [ ] 2- or 3-digit month
   - [ ] 4-digit year

3. **Sex**
   - [ ] Female
   - [ ] Male

4. **Weight**
   - [ ] 1 lb
   - [ ] 2 lb
   - [ ] 3 lb

   - [ ] 4 lb
   - [ ] 5 lb
   - [ ] 6 lb

   - [ ] 7 lb
   - [ ] 8 lb
   - [ ] 9 lb

   - [ ] 10 lb

   - [ ] 11 lb
   - [ ] 12 lb
   - [ ] 13 lb

   - [ ] 14 lb
   - [ ] 15 lb
   - [ ] 16 lb

   - [ ] 17 lb
   - [ ] 18 lb
   - [ ] 19 lb

   - [ ] 20 lb

5. **a. Ethnicity**
   - [ ] American Indian or Alaskan Native
   - [ ] Black or African American
   - [ ] Asian
   - [ ] Hispanic/Latino
   - [ ] Other
   - [ ] Native Hawaiian or Other Pacific Islander

6. **b. Race**
   - [ ] American Indian or Alaskan Native
   - [ ] Black or African American
   - [ ] Native Hawaiian or Other Pacific Islander
   - [ ] Asian
   - [ ] Hispanic/Latino
   - [ ] Other

### 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 Resulted from Adverse Event**
   - [ ] Death
   - [ ] Disability or Permanent Damage
   - [ ] Life-threatening
   - [ ] Hospitalization
   - [ ] Emergency Care
   - [ ] Other Serious (Important Medical Events)

3. **Date of Event (dd-mm-yyyy)**
   - 04-MM-YYYY

4. **Date of this Report (dd-mm-yyyy)**
   - 04-MM-YYYY

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**
   - See additional page(s) for complete text.

### C. PRODUCT AVAILABILITY

1. **Product Available for Evaluation?**
   - [ ] Yes
   - [ ] No
   - [ ] Returned to Manufacturer on:

### D. SUSPECT PRODUCTS

1. **Name, Manufacturer/Componder, Strength (from product label)**
   - [ ] Name
   - [ ] Manufacturer/Componder
   - [ ] Strength

2. **Lot #**
   - [ ] 1
   - [ ] 2

### E. SUSPECT MEDICAL DEVICE

1. **Brand Name**
2. **Serial #**
3. **Unique Identifier (UDI) #**
4. **Expiration Date (dd-mm-yyyy)**
5. **Catalog #**
6. **Lot #**
7. **Operator of Device**
   - [ ] Physician
   - [ ] Health Care Professional
   - [ ] Lay User/Patient
   - [ ] Other:

### F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1. **Name and Address**
2. **Phone #**
3. **E-mail**
4. **Zip/Postal Code**

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

1. **Address**
2. **City**
3. **State/Province/Region**
4. **Country**
5. **Phone #**
6. **E-mail**
7. **Zip/Postal Code**
8. **Address**
9. **City**
10. **State/Province/Region**
11. **Country**
12. **Phone #**
13. **E-mail**
14. **Zip/Postal Code**

### H. REPORTER (See confidentiality section on back)

1. **Address**
2. **City**
3. **State/Province/Region**
4. **Country**
5. **Phone #**
6. **E-mail**
7. **Zip/Postal Code**
8. **Address**
9. **City**
10. **State/Province/Region**
11. **Country**
12. **Phone #**
13. **E-mail**
14. **Zip/Postal Code**

### I. REPORTER (See confidentiality section on back)

1. **Address**
2. **City**
3. **State/Province/Region**
4. **Country**
5. **Phone #**
6. **E-mail**
7. **Zip/Postal Code**
8. **Address**
9. **City**
10. **State/Province/Region**
11. **Country**
12. **Phone #**
13. **E-mail**
14. **Zip/Postal Code**

### J. REPORTER (See confidentiality section on back)

1. **Address**
2. **City**
3. **State/Province/Region**
4. **Country**
5. **Phone #**
6. **E-mail**
7. **Zip/Postal Code**
8. **Address**
9. **City**
10. **State/Province/Region**
11. **Country**
12. **Phone #**
13. **E-mail**
14. **Zip/Postal Code**
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)

**EX 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 into 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,

[Signature]

Lyle Canida, Pharm.D., M.S.
LCR, 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
FACTS Interface

FACTS Complaint #146492 (CAERS #199664)

<table>
<thead>
<tr>
<th>Complaint Date</th>
<th>08/01/2016</th>
<th>Complaint Source</th>
<th>Consumer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accomplishing District</td>
<td>LOS-DO</td>
<td>Complaint Status</td>
<td>Archived</td>
</tr>
<tr>
<td>How Received</td>
<td>Phone Call</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Complainant Identification

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

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 mammal'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

<table>
<thead>
<tr>
<th>Symptom Name</th>
<th>Duration</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hair breakage</td>
<td>null null</td>
<td>Hair loss &amp; breakage</td>
</tr>
<tr>
<td>NEC - Identify in Remarks</td>
<td>null null</td>
<td>Red itchy lesions which scab over, burnt eyelashes, pesty nasal mucus</td>
</tr>
</tbody>
</table>

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

Product and Labeling

<p>| Brand Name | Brazilian Blowout |
| Product Name | Hair Straightener |
| FDA Product Code | 53ED03 |
| UPC Code | Qty/Unit |
|          | Package       |</p>
<table>
<thead>
<tr>
<th>Exp/Use By Date</th>
<th>Unknown</th>
<th>Lot/Serial</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Used?</td>
<td>Yes</td>
<td>Purchase Date</td>
<td>2015 &amp; 2016</td>
</tr>
<tr>
<td>Date Used?</td>
<td>5/12/2016</td>
<td>Amount Consumed/Used</td>
<td></td>
</tr>
<tr>
<td>Amount Remained</td>
<td>N/A</td>
<td>Date Discontinued</td>
<td></td>
</tr>
<tr>
<td>Country of Origin</td>
<td></td>
<td>Imported Product?</td>
<td>No</td>
</tr>
<tr>
<td>Retailer Name</td>
<td>Panico Salon</td>
<td>Label Remarks</td>
<td>No specific product information provided</td>
</tr>
</tbody>
</table>

**Manufacturer/Distributor**

<table>
<thead>
<tr>
<th>FEI</th>
<th>Name &amp; Address</th>
<th>Home District</th>
<th>Firm Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>30005750072</td>
<td>Brazilian Blowout 10615 W Vanowen St Burbank CA 91505-1136</td>
<td>LO3-DO</td>
<td>Warehouse-Ambient Storage</td>
</tr>
</tbody>
</table>

**Initial Evaluation / Initial Disposition**

<table>
<thead>
<tr>
<th>Initial Evaluation</th>
<th>FDA Action Indicated</th>
<th>Initial Disposition</th>
<th>Referred to Other FDA District</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposition Date</td>
<td>08/05/2016</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Remarks**

VM left for complainant on 6/1/2016 by CCV requesting additional information. Email sent to complainant on 6/2/2016 at NUrstitt@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**

<table>
<thead>
<tr>
<th>Cosmetic ID (b) (6)</th>
<th>DOB</th>
<th>Gender</th>
<th>Age</th>
<th>Race</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Place</td>
<td>Salon/SPA</td>
<td>Reason for Use</td>
<td>Other Products?</td>
<td>Hair Preparations (Non-Coloring)</td>
</tr>
<tr>
<td>Application Site</td>
<td>Scalp</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directions Followed?</td>
<td>Yes</td>
<td>Product Duration</td>
<td>Reaction Site</td>
<td>Scalp</td>
</tr>
<tr>
<td>Frequency of Use</td>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Use in Off-Label Manner?</td>
<td>No</td>
<td>Off-Label Manner Desc</td>
<td>Warning Statements?</td>
<td></td>
</tr>
<tr>
<td>Warning Statement on Label?</td>
<td>Warning Statements?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preexisting Conditions?</td>
<td>No</td>
<td>Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Adverse Events**

There is no adverse event information listed for this consumer complaint report.
October 24, 2016

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 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
For VOLUNTARY reporting of adverse events, product problems and product use errors
Page 1 of 2

A. PATIENT INFORMATION
1. Patient Identifier: [Patient ID]
2. Age at Time of Event: [Age]
3. Sex: [Male/Female]
4. Weight: [Weight]

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. Adverse Event
2. Product Problem (e.g., defects, malfunctions)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   - Death
   - Life-threatening
   - Dying
   - Severe injury or permanent damage
   - Hospitalization
   - Other Serious (Impairment/Death)
   - Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): [Date]
4. Date of this Report (mm/dd/yyyy): [Date]

5. Describe Event, Problem, or Product Use Error
Caller wanted to report an adverse event after a Brazilian Blowout Treatment. She has had these treatments in the past without problem. In 2015 she went to 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 straightener the hair gets. When the caller washed her hair she noticed hair right on her nails were missing and that her hair damaged. Lesions appeared on legs. She ended up going to another salon which to cut her because was too much damage. For months the caller let her grow out again. And in April after consulting with a 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 back. Again she had outcome hair breakup. She said since then she has thick mucus in her nostrils. Caller says that she has anxiety about her appearance now. She says a prior Brazilian Blowout in April she received a hair 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 Purchase? [Yes/No]

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label):
   - Brazilian Blowout
   - [Manufacturer]

2. Dose or Amount:

3. Date of Use (If unknown, give duration) (mm/dd/yyyy): [Date]

4. Diagnosis or Reason for Use (Indication):

5. Event Abated After Use Stopped or Does Not Apply?
   - Yes
   - No
   - Doesn't Apply

6. Event Reappeared After Reintroduction?
   - Yes
   - No
   - Doesn't Apply

7. Expiration Date (mm/dd/yyyy): [Date]

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. SUSPECT MEDICAL DEVICE
1. Brand Name:
2. Common Device Name:
3. Manufacturer Name, City and State:
4. Model #:
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):

G. REPORTER (See confidentiality section on back)
1. Name and Address:
   - [Name/Address]

2. Phone #:
   - (b) (6)

3. E-mail:

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

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