September 27, 2016

BRAZILIAN BLOWOUT
28001 DOROTHY DR
AGOURA HILLS, California 91301

To Whom It May Concern:

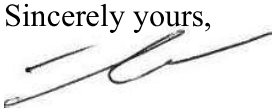
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 199772.

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

Sincerely yours,



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

Enclosure

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Internet Consumer Report CFSAN

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

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

FDA USE ONLY	
Triage unit sequence #	6728606
FDA Rec. Date	

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

A. PATIENT INFORMATION

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

2. **Age** 47 ☑ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)
or Date of Birth *(e.g., 08 Feb 1925)*

3. **Sex** ☑ Female ☐ Male

4. **Weight** 130 ☑ lb ☐ kg

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

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

B. ADVERSE EVENT, PRODUCT PROBLEM

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

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

3. **Date of Event** *(dd-mmm-yyyy)* 05-Aug-2016

4. **Date of this Report** *(dd-mmm-yyyy)* 06-Aug-2016

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

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

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

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCTS

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

#1 - Name and Strength	#1 - NDC # or Unique ID
Cezanne Perfect Finnish Keratin	
#1 - Manufacturer/Compounder	**#1- Lot #**
Cezanne	
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

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

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 05-Aug-2016 - 05-Aug-2016
#2

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

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

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

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

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

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

2b. **Procode** CTU

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

AUG - 8 2016

4. **Model #**

Lot #

Catalog #

Expiration Date *(dd-mmm-yyyy)*

Serial #

Unique Identifier (UDI) #

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

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

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

3. **Occupation**

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

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

PLEASE TYPE OR USE BLACK INK

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

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

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

none

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

Medical Conditions: none

Allergies: none

Important Information: healthy, no medications

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

RX Meds: none

OTC Meds: sometimes Tums, vitamin D, ibuprofen

U.S. Department of Health and Human Services

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☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* _____
☐ Life-threatening
☐ Hospitalization - initial or prolonged
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3. **Date of Event** *(dd-mmm-yyyy)* 05-Aug-2016

4. **Date of this Report** *(dd-mmm-yyyy)* 06-Aug-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.

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

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#1 - Name and Strength	#1 - NDC # or Unique ID
Cezanne Perfect Finnish Keratin	
#1 - Manufacturer/Compounder	**#1- Lot #**
Cezanne	
#2 - Name and Strength	**#2 - NDC # or Unique ID**
#2 - Manufacturer/Compounder	**#2- Lot #**

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

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 05-Aug-2016 - 05-Aug-2016
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5. **Diagnosis or Reason for Use** *(indication)*
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#1 ☐ Yes ☑ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

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

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

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

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

2b. **Procode** CTU

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

AUG - 8 2016

4. **Model #**

Lot #

Catalog #

Expiration Date *(dd-mmm-yyyy)*

Serial #

Unique Identifier (UDI) #

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

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

3. **Occupation**

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

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PLEASE TYPE OR USE BLACK INK

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

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

none

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

Medical Conditions: none

Allergies: none

Important Information: healthy, no medications

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

RX Meds: none

OTC Meds: sometimes Tums, vitamin D, ibuprofen

October 21, 2016

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

To Whom It May Concern:

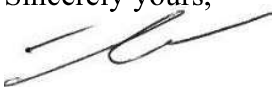
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 199927.

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

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

Basic Details

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

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date of Death	
Date the problem occurred	13-Jul-2016

Tell us what happened and how it happened (Include as many details as possible)

I had a Brazilian Blowout on my hair on July 13, 2016. By the next day I had an itchy face, numbness/tingling feeling on my face and flu like symptoms with nausea and diarrhea. I contacted my hairdresser and she had never heard of such symptoms. After 1 week of dealing with these symptoms I asked if I could get the product removed from my hair. My hairdresser contacted the company and was able to get me the MSDS and was told to use their anti-residue shampoo to wash it out. My first wash out was on July 23, 2016 . I continued having symptoms and they progressed over time to have periods of itchy/numbness throughout my entire body,. I have had several Dr's appointments as a result and have had my hair dresser try to wash it out several times. Below is a summary of Dr's appointment's to date

List any relevant tests or laboratory data if you know them (Include dates)

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	BRAZILIAN BLOWOUT AÇAI PROFESSIO		
Name of the company that makes (or compounds) the product	Brazilian Blowout		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	Yes		
Is the Product Over-the-Counter?			
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency		**If Other**	
How was it taken or used	Other	**If Other**	hair
Date the person first started taking or using the product			
Date the person stopped taking or using the product			
Did the problem stop after the person reduced the dose or stopped taking or using the			

product?	
Did the problem return if the person started taking or using the product again?	
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	
Date of Birth	(b) (6)
Weight	
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

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

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

neurontin

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

zyrtec

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	06-Oct-2016
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐

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

Basic Details

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

Contact

Source Form Type	First Name	Last Name	Email Address	Phone
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Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
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product?	
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Do you still have the product in case we need to evaluate it?	No

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Please list all allergies (such as to drugs, foods, pollen or others)

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neurontin

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zyrtec

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
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State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	06-Oct-2016
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐

November 08, 2016

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

To Whom It May Concern:

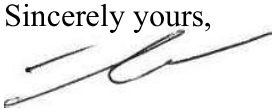
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 202704.

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

Sincerely yours,



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

Enclosure

Receipt No: RCT-10349

203353

FDA 3500B Form

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

Basic Details

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

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident
Date of Death	
Other serious/important medical incident	
Date the problem occurred	23-Oct-2016

Tell us what happened and how it happened (Include as many details as possible)

I received a keratin treatment and experienced coughing, watering of the eyes and burning of the nose and throat.

List any relevant tests or laboratory data if you know them (Include dates)

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Keratin		
Name of the company that makes (or compounds) the product			
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?			
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency		**If Other**	
How was it taken or used		**If Other**	
Date the person first started taking or using the product	22-Oct-2016		
Date the person stopped taking or using the product			
Did the problem stop after the			

person reduced the dose or stopped taking or using the product?	
Did the problem return if the person started taking or using the product again?	
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

Keratin treatment in a hair salon

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	41 Year(s)
Date of Birth	
Weight	91.35 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☑ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ White ☑ Black or African American

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

Diabetes and high blood pressure

Please list all allergies (such as to drugs, foods, pollen or others)

Eggs, Bactrim, sulfa drugs, rocephrin

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

Metforim, losartan

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	23-Oct-2016
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity	☐

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

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

Basic Details

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

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
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Date of Death	
Other serious/important medical incident	
Date the problem occurred	23-Oct-2016

Tell us what happened and how it happened (Include as many details as possible)

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List any relevant tests or laboratory data if you know them (Include dates)

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Keratin		
Name of the company that makes (or compounds) the product			
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?			
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency		**If Other**	
How was it taken or used		**If Other**	
Date the person first started taking or using the product	22-Oct-2016		
Date the person stopped taking or using the product			
Did the problem stop after the			

person reduced the dose or stopped taking or using the product?	
Did the problem return if the person started taking or using the product again?	
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

Keratin treatment in a hair salon

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	41 Year(s)
Date of Birth	
Weight	91.35 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☑ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☐ **White** ☑ **Black or African American**

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

Diabetes and high blood pressure

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Eggs, Bactrim, sulfa drugs, rocephrin

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

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Metforim, losartan

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	23-Oct-2016
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity	☐

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

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

Basic Details

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

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
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Date of Death	
Other serious/important medical incident	Drowsiness, sinus irritation
Date the problem occurred	20-Nov-2016

Tell us what happened and how it happened (Include as many details as possible)

I was having my hair cut at a salon where another customer was having a Brazilian blow out in the next chair, and I was exposed to the fumes from her treatment which left me feeling awful for 6 hours after I left the salon. The adverse effects I experienced included sinus irritation, tiredness, headache and dizziness.

List any relevant tests or laboratory data if you know them (Include dates)

None

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout		
Name of the company that makes (or compounds) the product	GIB, LLC		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency	Other	**If Other**	Once
How was it taken or used	Topical	**If Other**	
Date the person first started taking or using the product	20-Nov-2016		
Date the person stopped taking or using the product	20-Nov-2016		
Did the problem stop after the	Yes		

person reduced the dose or stopped taking or using the product?	
Did the problem return if the person started taking or using the product again?	Doesn't Apply
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

Treatment for straightening hair in a salon

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	SW
Sex	Female
Age (specify unit of time for age)	44 Year(s)
Date of Birth	
Weight	53.1 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☑ **Asian** ☐ **White** ☐ **Black or African American**

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

None, healthy

Please list all allergies (such as to drugs, foods, pollen or others)

None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

Heathy

List all current prescription medications and medical devices being used.

None

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Ibuprofen

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	
Email address	(b) (6)
Today's date	20-Nov-2016
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity	☐

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Basic Details

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

Contact

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

Section A - About the Problem

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Date of Death	
Other serious/important medical incident	Drowsiness, sinus irritation
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Tell us what happened and how it happened (Include as many details as possible)

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None

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout		
Name of the company that makes (or compounds) the product	GIB, LLC		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency	Other	**If Other**	Once
How was it taken or used	Topical	**If Other**	
Date the person first started taking or using the product	20-Nov-2016		
Date the person stopped taking or using the product	20-Nov-2016		
Did the problem stop after the	Yes		

person reduced the dose or stopped taking or using the product?	
Did the problem return if the person started taking or using the product again?	Doesn't Apply
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

Treatment for straightening hair in a salon

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

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Date the implant was put in		**Date the implant was taken out (If relevant)**	

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Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	44 Year(s)
Date of Birth	
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Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☑ **Asian** ☐ **White** ☐ **Black or African American**

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

None, healthy

Please list all allergies (such as to drugs, foods, pollen or others)

None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

Heathy

List all current prescription medications and medical devices being used.

None

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Ibuprofen

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	
Email address	(b) (6)
Today's date	20-Nov-2016
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity	☐

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

January 30, 2017

GIB LLC
6855 Tujunga Ave.
North Hollywood, California 91605

To Whom It May Concern:

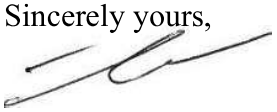
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 204550.

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

Sincerely yours,



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

Enclosure

[Close]

FACTS Interface

FACTS Complaint #147718 (CAERS #204959)

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

Complainant Identification

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

Complaint / Injury

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

Adverse Event Result	Non-serious Injuries/ Illness
Adverse Event Date	10/31/2016
Notify EIO/EMOPS?	Yes
Notification Date	11/22/2016
Attended Health Professional?	Unknown
Required Hospitalization?	No
Emergency Room/ Outpatient Visit?	No
Reported Complaint To?	FDA
Need Additional/ FDA Contact?	

Remarks
See below****Authorized to forward

Complaint Symptoms

Symptom Name	Duration	Remarks
Burning	null null	Burning eyes
Difficulty breathing	null null	
Local swelling	null null	Swollen eyes
NEC - Identify in Remarks	1 Day(s)	Nose bleed
Rash	null null	rash at face

Health Care Professional

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

Product and Labeling

Brand Name	Rejuvenol		
Product Name	Keratin Treatment		
FDA Product Code	53EC03	**Qty/Unit**	
UPC Code	UNK	**Package**	
Exp/Use By Date	UNK	**Lot/Serial**	UNK
Product Used?	No	**Purchase Date**	UNK
Date Used?	10/30/2016	**Amount Consumed/Used**	UNK
Amount Remained	UNK	**Date Discontinued**	10/30/2016
Country of Origin		**Imported Product?**	No
Retailer Name	Neo Blow & Color Hair Salon	**Label Remarks**	

Manufacturer/Distributor

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

Initial Evaluation / Initial Disposition

Initial Evaluation Insuffici. Info, unable to evaluate **Initial Disposition** Closed w/o further Investigation
Disposition Date 12/06/2016
Remarks
www.rejuvenol.com ---- 12/6/16 to date no response.*****Will be referred to DOH at Nassau for their follow up as deemed necessary.

Problem Keyword	Problem Keyword Details
Reaction	Experienced difficulty breathing, nose bleed, rash at face, burning and swelling of eyes

Cosmetic

Cosmetic ID #25564

DOB		**Age**	28
Gender	Female	**Race**	White
Application Place	Salon/SPA	**Reason for Use**	Hair Preparations (Non-Coloring)
Application Site	Face	**Other Products?**	
Directions			
Directions Followed?	Yes	**Product Duration**	
Frequency of Use	Other	**Reaction Site**	Face
Product Use in Off-Label Manner?	No	**Off-Label Manner Desc**	
Warning Statement on Label?		**Warning Statements?**	
Preexisting Conditions?	No	**Treatment**	Physician
Current Status	Unchanged		

Medical Diagnosis
Unknown
Medical Treatment
Cream
Remarks
Frequency is every six weeks

Adverse Events

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

[Close]

February 17, 2017

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

To Whom It May Concern:

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

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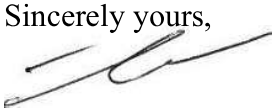
To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 204959.

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

Sincerely yours,



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

Enclosure

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Page 1 of 1

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

FDA USE ONLY
Triage unit sequence # 206021

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

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

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	01/06/2017

5. Describe Event, Problem or Product Use Error

Caller says she'd used Wen Fig Cleansing Conditioner three years ago and liked it. She recently tried it again and experienced a different result. During the three weeks of use there was shedding and her hair was falling out in clumps. So much so that she began collecting it in baggies. It was only used for three weeks and she was suspicious that WEN was the cause of her hair loss as there had been no other change in her life, health or medications. She contacted Gunthy-Renker and person on phone told her the formulations were different dependent upon whether it was produced for QVC, Gunthy-Renker, for sale Canada, or the international market. She believes this is fraud. Whilst the information conveys ingredients as all natural, the actual product sold contains ingredients that are not. She contacted WEN who said they could not tell her the ingredients since they've change formulas they have no record. She says the ingredients are difficult to see on her product. She believes lead, parabens, or formaldehyde to be an ingredient used in this product is being used to maximum profit. However, it lowers the quality of the product and it is deceptive. The caller is a license hair stylist and has been for many years.

6. Relevant Tests/Laboratory Data, Including Dates

The caller is a license hair stylist and has been for many years. She is certain an unsafe ingredient is being used. She says Chaz Dean recently sent her an email offering to pay her $25 as settlement.

The unused portion of the product is available for testing.

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

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Wen Cleansing Conditioner Fall Series
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

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

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. Name and Address
(b) (6)

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

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Non-Healthcare Professional	☑ 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.

January 30, 2017

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

To Whom It May Concern:

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

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

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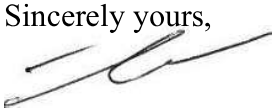
If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,



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

Enclosure

Receipt No: RCT-29542 **FDA 3500B Form**

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

Basic Details

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

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date of Death	
Date the problem occurred	28-Jan-2017

Tell us what happened and how it happened (Include as many details as possible)

While working in a salon, a fellow stylist performed a Brazilian Blow Out on a girl. With no proper ventilation. Only bringing out a fan and opening the back door 3/4 of the way through the initial blow drying and flat ironing. While all the chemicals were being released through the heating process. She was using the Brazilian Blow Out Original formula, not the Zero. Immediately eyes and my nose were starting to burn. I couldn't leave because I still had clients. This resulted in prolonged exposure without ventilation. By the time I left, I could tell that my sinuses were quite effected. My eyes still burn today and I'm on sinus medication. I may have to start a steroid if the medication doesn't work. Also, lots of sneezing.

List any relevant tests or laboratory data if you know them (Include dates)

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian BlowOut Acai Professio		
Name of the company that makes (or compounds) the product	Brazilian BlowOut		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?			
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)	11.8 % percent	**If Other**	
Quantity		**If Other**	
Frequency		**If Other**	
How was it taken or used	Other	**If Other**	Hair
Date the person first started taking or using the product	28-Jan-2017		
Date the person stopped taking or using the product			
Did the problem stop after the person reduced the dose or stopped taking or using the			

product?	
Did the problem return if the person started taking or using the product again?	
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

Curly hair

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	38 Year(s)
Date of Birth	
Weight	
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

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

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	
City	
State/Province	(b) (6)
Country	USA
ZIP or Postal code	
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	01-Feb-2017
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐

May 03, 2017

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

To Whom It May Concern:

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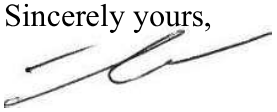
If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,



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

Enclosure

Receipt No: RCT-29568 **FDA 3500B Form**

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

Basic Details

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

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☑ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident
Date of Death	
Other serious/important medical incident	
Date the problem occurred	01-Feb-2017

Tell us what happened and how it happened (Include as many details as possible)

I had a Brazilian blowout treatment and while I was in the chair my whole body and face broke out in hives -- there was no ventilation

List any relevant tests or laboratory data if you know them (Include dates)

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout		
Name of the company that makes (or compounds) the product	Brazilian blowout		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency		**If Other**	
How was it taken or used	Topical	**If Other**	
Date the person first started taking or using the product			
Date the person stopped taking or using the product			
Did the problem stop after the	Yes		

person reduced the dose or stopped taking or using the product?	
Did the problem return if the person started taking or using the product again?	
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

Curly hair

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	28 Year(s)
Date of Birth	
Weight	56.25 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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

None

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

None

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

None

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	01-Feb-2017
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity	☐

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

May 03, 2017

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

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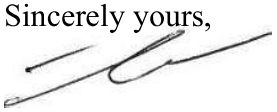
If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,



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

Enclosure

Receipt No: RCT-30339 **FDA 3500B Form**

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

Basic Details

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

Contact

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

Receipt No: RCT-30339 **FDA 3500B Form**

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date of Death	
Date the problem occurred	03-Feb-2017

Tell us what happened and how it happened (Include as many details as possible)

Severe red open rash on scalp. Severe itch.

List any relevant tests or laboratory data if you know them (Include dates)

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Tresemme Keratin Smooth		
Name of the company that makes (or compounds) the product	Unilever		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number	05136JU34		
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity	Other	**If Other**	25 Ounce(s)
Frequency		**If Other**	
How was it taken or used	Other	**If Other**	Hair shampoo
Date the person first started taking or using the product	27-Jan-2017		
Date the person stopped taking or using the product	04-Feb-2017		
Did the problem stop after the person reduced the dose or stopped taking or using the	Yes		

product?	
Did the problem return if the person started taking or using the product again?	Yes
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

Shampoo hair

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	47 Year(s)
Date of Birth	
Weight	
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

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

Receipt No: RCT-30339 **FDA 3500B Form**

Please list all allergies (such as to drugs, foods, pollen or others)

Levaquin

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	
Email address	(b) (6)
Today's date	04-Feb-2017
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐

May 30, 2017

UNILEVER UNITED STATES, INC.
920 Sylvan Avenue
Englewood Cliffs, New Jersey 07632-3313

To Whom It May Concern:

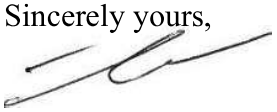
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 207239.

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

Sincerely yours,



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

Enclosure

Receipt No: RCT-35880

FDA 3500B Form

Related reports

208370

212727 - Anonymous 1

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

Basic Details

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

Contact

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

Receipt No: RCT-35880 **FDA 3500B Form**

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date of Death	
Date the problem occurred	23-Feb-2017

Tell us what happened and how it happened (Include as many details as possible)

I am a hairstylist that works in salon that is part of a large chain of salons. We use a Keratin style hair smoother/straightener in our salon. The brand name is Liquid Keratin. The first time I used the product I felt ill. I have experienced horrible pressure in my head followed by a headache and sore throat that burned for days. At times I would feel extremely lightheaded. Each subsequent time I used the product I became ill with the same symptoms. These symptoms would continue to get worse even hours after the service was completed. It is during the blow dry process and flat iron stage that I begin to feel the onset of symptoms. Other stylists in the salon have felt the serious and adverse side effects as well. Burning eyes, almost fainting, headaches.

List any relevant tests or laboratory data if you know them (Include dates)

Liquid Keratin claims to be "formaldehyde free." The manufacturers directions state to heat the flat iron to 420 to 450 degrees during the treatment. The MSDS states nothing about the chemical changes caused by the heat. There are no warnings on the label. Glyoxyloyl carbocysteine is the second ingredient listed on the bottle.

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Liquid Keratin		
Name of the company that makes (or compounds) the product	Liquid Keratin		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity	Other	**If Other**	1 Ounce(s)
Frequency	Other	**If Other**	At client request
How was it taken or used	Other	**If Other**	Applied to the hair
Date the person first started taking or using the product	19-Aug-2015		
Date the person stopped taking or using the product	23-Feb-2017		
Did the problem stop after the person reduced the dose or stopped taking or using the	Yes		

product?	
Did the problem return if the person started taking or using the product again?	Yes
Do you still have the product in case we need to evaluate it?	Yes

Why was the person using the product? (such as what condition was it supposed to treat)

Hair Smoothing

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	46 Year(s)
Date of Birth	
Weight	
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

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

Receipt No: RCT-35880 **FDA 3500B Form**

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	USA
ZIP or Postal code	
Telephone number	
Email address	
Today's date	01-Mar-2017
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☑

Receipt No: RCT-35880 **FDA 3500B Form**

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

Basic Details

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

Contact

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

Receipt No: RCT-35880 **FDA 3500B Form**

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date of Death	
Date the problem occurred	23-Feb-2017

Tell us what happened and how it happened (Include as many details as possible)

I am a hairstylist that works in salon that is part of a large chain of salons. We use a Keratin style hair smoother/straightener in our salon. The brand name is Liquid Keratin. The first time I used the product I felt ill. I have experienced horrible pressure in my head followed by a headache and sore throat that burned for days. At times I would feel extremely lightheaded. Each subsequent time I used the product I became ill with the same symptoms. These symptoms would continue to get worse even hours after the service was completed. It is during the blow dry process and flat iron stage that I begin to feel the onset of symptoms. Other stylists in the salon have felt the serious and adverse side effects as well. Burning eyes, almost fainting, headaches.

List any relevant tests or laboratory data if you know them (Include dates)

Liquid Keratin claims to be "formaldehyde free." The manufacturers directions state to heat the flat iron to 420 to 450 degrees during the treatment. The MSDS states nothing about the chemical changes caused by the heat. There are no warnings on the label. Glyoxyloyl carbocysteine is the second ingredient listed on the bottle.

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Liquid Keratin		
Name of the company that makes (or compounds) the product	Liquid Keratin		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity	Other	**If Other**	1 Ounce(s)
Frequency	Other	**If Other**	At client request
How was it taken or used	Other	**If Other**	Applied to the hair
Date the person first started taking or using the product	19-Aug-2015		
Date the person stopped taking or using the product	23-Feb-2017		
Did the problem stop after the person reduced the dose or stopped taking or using the	Yes		

product?	
Did the problem return if the person started taking or using the product again?	Yes
Do you still have the product in case we need to evaluate it?	Yes

Why was the person using the product? (such as what condition was it supposed to treat)

Hair Smoothing

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	46 Year(s)
Date of Birth	
Weight	
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

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

Receipt No: RCT-35880 **FDA 3500B Form**

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	USA
ZIP or Postal code	
Telephone number	
Email address	
Today's date	01-Mar-2017
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☑

June 12, 2017

LIQUID KERATIN INC
101 King High Ave
Toronto, ON
Canada

To Whom It May Concern:

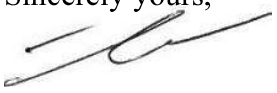
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 208370.

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

Sincerely yours,



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

Enclosure

Receipt No: RCT-40789 **FDA 3500B Form**

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

Basic Details

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

Contact

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

Receipt No: RCT-40789 **FDA 3500B Form**

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident
Date of Death	
Other serious/important medical incident	Dizziness,faint,confusion
Date the problem occurred	22-Mar-2017

Tell us what happened and how it happened (Include as many details as possible)

I work in a hair salon. I was cutting my clients hair and began to feel dizzy.. I tried to keep my balance and readjust my head position so I wouldn't fall back. My heart started to race and I felt faint. I didn't know what I was saying or doing I just wanted to finish my client to sit down. I started to feel nauseous and finally left my station. After a few minutes I returned to my station and the feelings came back.. I had to shut my eyes and couldn't talk.. I realized another stylist was doing a Brazilian Blowout near me.. I immediately left.. my symptoms slowly got better.. My eyes were burning and my nose and throat are very dry/scratchy. Even into the evening.. Mu salon started to carry the Brazilian blowout over the past 6-8 months and I have had mild dizziness before but never understood why or how.. but it has only been at work within that time frame. Never anywhere else!

List any relevant tests or laboratory data if you know them (Include dates)

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout		
Name of the company that makes (or compounds) the product			
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?			
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency		**If Other**	
How was it taken or used	Respiratory (inhalation)	**If Other**	
Date the person first started taking or using the product			
Date the person stopped taking or using the product	15-Sep-2016		

Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes
Did the problem return if the person started taking or using the product again?	Yes
Do you still have the product in case we need to evaluate it?	Yes

Why was the person using the product? (such as what condition was it supposed to treat)

Hair frizz

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	43 Year(s)
Date of Birth	
Weight	67.5 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

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

Please list all allergies (such as to drugs, foods, pollen or others)

Seasonal

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Daily gummy vitamin

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	(b) (6)
Did you report this problem to the company that makes the product	No

(the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐

Receipt No: RCT-53393 **FDA 3500B Form**

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

Basic Details

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

Contact

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

Receipt No: RCT-53393 **FDA 3500B Form**

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date of Death	
Date the problem occurred	12-Apr-2017

Tell us what happened and how it happened (Include as many details as possible)

I received a keratin hair treatment on April 12th, 2017 and I've been sick ever since. I had a metallic taste of my mouth for three weeks, I've been dizzy, faint, nauseous, having heart palpitations and digestive issues. I actually bought a tongue scraper to take off the taste in my mouth. Since then, I'm extremely sensitive to any type of chemical smell even Tide detergent pods. Anything that has a low, medium or high VOC affects me. I'm deeply concerned that the product I used has formaldehyde in it that may have caused this reaction. I bought the product from Amazon last May 2016. I didn't use it right away because I didn't need it until one month ago before taking a vacation in Costa Rica. I had two sets of blood work done: one on April 24th and one on May 9th and there are abnormalities especially with my red blood cells. There is no ingredient list on the bottle nor on Amazon. I would like to get the product tested to find out if I've been exposed to high amounts of formaldehyde. Every time I wash my hair the smell emits into the air, so I've been going 1 - 2 weeks without washing my hair because I'm concerned about getting worse. I'm still under a doctor's care to figure this out. I would like to have the product tested to find out what's in it. I need to resolve the way I'm feeling as I need to work and be functional.

List any relevant tests or laboratory data if you know them (Include dates)

I have blood tests from my doctor; I'm still under his care and would like to get to the bottom of this challenge.

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Kera Fruit		
Name of the company that makes (or compounds) the product	Kera Fruit		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency		**If Other**	
How was it taken or used	Other	**If Other**	As a hair treatment to control frizz
Date the person first started taking or using the product	12-Apr-2017		
Date the person stopped taking or			

using the product	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No
Did the problem return if the person started taking or using the product again?	Doesn't Apply
Do you still have the product in case we need to evaluate it?	Yes

Why was the person using the product? (such as what condition was it supposed to treat)

To control frizz and smooth my hair

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	49 Year(s)
Date of Birth	
Weight	49.5 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

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

Hypothyroid

Please list all allergies (such as to drugs, foods, pollen or others)

Penicillin, pollen, rag weed, mold, oak trees, dust

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

I'm a very healthy person that eats mostly organic vegetables and fish. I'm also a integrative health coach.

List all current prescription medications and medical devices being used.

Nature Thyroid

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Nothing

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Today's date	15-May-2017
Did you report this problem to the company that makes the product	No

(the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☑

Receipt No: RCT-35880

FDA 3500B Form

Related reports

208370

212727 - Anonymous 1

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

Basic Details

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

Contact

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

Receipt No: RCT-35880 **FDA 3500B Form**

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date of Death	
Date the problem occurred	23-Feb-2017

Tell us what happened and how it happened (Include as many details as possible)

I am a hairstylist that works in salon that is part of a large chain of salons. We use a Keratin style hair smoother/straightener in our salon. The brand name is Liquid Keratin. The first time I used the product I felt ill. I have experienced horrible pressure in my head followed by a headache and sore throat that burned for days. At times I would feel extremely lightheaded. Each subsequent time I used the product I became ill with the same symptoms. These symptoms would continue to get worse even hours after the service was completed. It is during the blow dry process and flat iron stage that I begin to feel the onset of symptoms. Other stylists in the salon have felt the serious and adverse side effects as well. Burning eyes, almost fainting, headaches.

List any relevant tests or laboratory data if you know them (Include dates)

Liquid Keratin claims to be "formaldehyde free." The manufacturers directions state to heat the flat iron to 420 to 450 degrees during the treatment. The MSDS states nothing about the chemical changes caused by the heat. There are no warnings on the label. Glyoxyloyl carbocysteine is the second ingredient listed on the bottle.

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Liquid Keratin		
Name of the company that makes (or compounds) the product	Liquid Keratin		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity	Other	**If Other**	1 Ounce(s)
Frequency	Other	**If Other**	At client request
How was it taken or used	Other	**If Other**	Applied to the hair
Date the person first started taking or using the product	19-Aug-2015		
Date the person stopped taking or using the product	23-Feb-2017		
Did the problem stop after the person reduced the dose or stopped taking or using the	Yes		

product?	
Did the problem return if the person started taking or using the product again?	Yes
Do you still have the product in case we need to evaluate it?	Yes

Why was the person using the product? (such as what condition was it supposed to treat)

Hair Smoothing

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	46 Year(s)
Date of Birth	
Weight	
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

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

Receipt No: RCT-35880 **FDA 3500B Form**

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	USA
ZIP or Postal code	
Telephone number	
Email address	
Today's date	01-Mar-2017
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☑

June 12, 2017

LIQUID KERATIN INC
101 King High Ave
Toronto, ON
Canada

To Whom It May Concern:

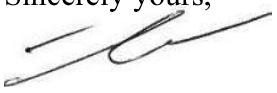
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5001 Campus Drive, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 212727.

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

Sincerely yours,



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

Enclosure

Receipt No: RCT-64680 **FDA 3500B Form**

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

Basic Details

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

Contact

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

Receipt No: RCT-64680 **FDA 3500B Form**

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date of Death	
Date the problem occurred	31-Jul-2016

Tell us what happened and how it happened (Include as many details as possible)

Received a Brazilian Blowout Smoothing Treatment. Following the treatment, scalp was very sensitive. Massive amount of shedding took place. Scalp was red and itchy and burned. Have lost at least 60% of hair thickness. I still have hair loss from the bulb with little or no regrowth. I have miniaturized superfluous hairs and scalp is still red. My hair continues to thin and scalp goes from pink to beet red. Prior to the treatment, I had no scalp issues and long, extremely thick hair. There is no hair loss issues in any of my family members. I have been looking at hair toppers and starting to go through a deep depression. There are many blogs and support groups on line and many women are going through the same after Brazilian Blowout but no one is able to provide a solution to regrow our hair

List any relevant tests or laboratory data if you know them (Include dates)

I've been to 7 dermatologist and an acupuncturist. I had a scalp biopsy this week and am awaiting results. Most Doctors said it was telogen effluvium and would get better when the scalp inflammation is gone. No one is able to get rid of the inflammation. Almost one year now with red scalp and continued diffused hair loss.

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian Blowout		
Name of the company that makes (or compounds) the product	I don't know. It's from Hair salon		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?			
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency		**If Other**	
How was it taken or used	Topical	**If Other**	
Date the person first started taking or using the product	31-Jul-2016		
Date the person stopped taking or using the product	31-Jul-2016		
Did the problem stop after the person reduced the dose or stopped taking or using the	No		

product?	
Did the problem return if the person started taking or using the product again?	Doesn't Apply
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

Hair treatment at salon to smooth hair, eliminate frizz

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	64 Year(s)
Date of Birth	
Weight	49.05 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

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

Borderline high blood pressure

Receipt No: RCT-64680 **FDA 3500B Form**

Please list all allergies (such as to drugs, foods, pollen or others)

Macrodantin, keflex

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

Losartan 25mg

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Calcium, vitamin D, Biotin, Fish Oil, Grapeseed

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	USA
ZIP or Postal code	
Telephone number	
Email address	
Today's date	29-Jun-2017
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☑

From: The Rose Sheet
To: Katz, Linda
Subject: "The Rose Sheet" | This Week"s Issue
Date: Monday, September 22, 2014 4:07:16 AM

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Top Stories

Short Window For Senate, House To Agree On TEA Review Deadlines For FDA The Senate approves an amended version of the Sunscreen Innovation Act by unanimous consent, with a view toward speeding FDA reviews for all OTC ingredient TEAs. The House version addresses only sunscreen TEAs, and reconciliation of the two chambers' bills likely will have to wait for the lame duck session.
"The Rose Sheet" September 18 2014 9:50 AM

CIR Panel Rejects Safe Use Of Hydroquinone Under UV Nail Lights At its September meeting, the Cosmetic Ingredient Review Expert Panel concluded that hydroquinone's use in gel nail products is safe when LED lights are used in the curing process, but UV lights should not be used to set formulas due to concerns about skin-cancer risks. Separately, panel members issued a final amended assessment for preservative methylisothiazolinone, affirming their earlier tentative decision on the ingredient's safety in rinse-off and leave-in products.
"The Rose Sheet" September 22 2014 12:01 AM

California DTSC's Draft Work Plan Includes Personal Care, But Few Surprises California's Department of Toxic Substances has identified "beauty, personal care and hygiene" as one of seven product categories that could yield next-round priority product selections under the state's Safer Consumer Products regulations. PCPC's Associate General Counsel (b) (6) says there are no big surprises in the nomination or the candidate chemicals identified - including formaldehyde, lead and phthalates - and he welcomed the direction DTSC appears to be taking toward more active industry engagement over the next three years.
"The Rose Sheet" September 18 2014 3:55 PM

The Marketplace

Cosmetics Sector Increasingly Popular Class-Action Target During H1 2014 From January to June 2014, complaints against cosmetics firms accounted for 11% of total U.S. filings alleging unfair and deceptive acts and practices, compared with 7% in 2013, according to law firm Bryan Cave LLP. Most often filed in California state and federal courts, complaints target "natural" and performance claims, among others identified in a "Rose Sheet" infographic.
"The Rose Sheet" September 19 2014 10:40 AM

Business & Finance

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

Marketing/Advertising

***Olay* Can Claim Benefit Over, But Not "Harshness" Of, *Dove* Body Wash - NAD** P&G's LCAT testing is sufficient to support a claim in Olay Sensitive Body Wash ads that competing product Dove Sensitive Skin is more drying than water over time. However, the firm should discontinue claims that disparage the Dove offering as "harsh" or suggest that Dove Sensitive Skin users will perceive a drying effect upon contact or have noticeably drier skin with continued product use, NAD says.
"The Rose Sheet" September 22 2014 12:00 AM

NAD Rules On P&G Claims Comparing *Olay*, *Dove* Hydrating Body Washes Procter & Gamble's study data is sufficient to support claims that Olay Ultra Moisture Body Wash provides a greater long-term moisturization benefit compared with Unilever's Dove Deep Moisture, NAD rules. However, claims positioning the Olay product as a viable substitute for lotion should be discontinued, as should statements that tend to falsely disparage Unilever's competing body wash, the CBBB investigative unit says.
"The Rose Sheet" September 22 2014 12:00 AM

Trademarks

Weekly Trademark Review Sep 16, 2014 [Class 3 (Cosmetics and Cleaning Preps) compiled by "The Rose Sheet" from Official Gazette of the U.S. Patent and Trademark Office] Product Name Trademark No./ [Serial No.] Company Filed Date [Published] Class Nos.
"The Rose Sheet" September 22 2014 12:00 AM

From: The Rose Sheet
To: Katz, Linda
Subject: "The Rose Sheet" | This Week"s Issue
Date: Monday, October 6, 2014 4:06:15 AM

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Monday, October 06, 2014 | View in Browser | Forward to a Friend

Top Stories

Preservatives Identified As Sustainability Priority At Industry Summit

Held by Forum for the Future and co-hosted by Walmart and Target, the Sept. 4 Beauty and Personal Care Products Sustainability Summit facilitated discussion among entities throughout the supply chain regarding sustainability priorities and potential initiatives for improvement. Attendees identified development of new and alternative preservative systems as a key "idea for action," along with measures for enhanced communication and transparency around cosmetic ingredients.

FTC: All Advertisers Should Heed Lessons From "Operation Full Disclosure"

On the heels of FTC's "Operation Full Disclosure," which resulted in 60 warning letters, commission officials advise all advertisers to pay close attention to their disclosures and ensure they are clear and conspicuous. The initiative included review of 1,000 national television and print ads, and the agency says it will continue to monitor the advertising landscape for inadequate disclosure use.

Safe Cosmetics Campaign Prepares "Retailer Red List" Of 100 "Toxic" Chemicals

Within the next month, NGO will present retailers with a list of roughly 100 priority "toxic" chemicals it wants removed from personal-care products on store shelves, according to Campaign for Safe Cosmetics co-founder (b) (6) . Meanwhile, CSC has launched its "Cosmetics Without Cancer" initiative, with P&G as its initial target, part of an effort to reassess the market 10 years after creation of the Safe Cosmetics Compact.

Regulatory/Legislative

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

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

The Marketplace

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

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

Other

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

From: The Rose Sheet
To: Katz, Linda
Subject: "The Rose Sheet" | This Week"s Issue
Date: Monday, August 18, 2014 4:04:08 AM

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Top Stories

FDA Studies Trace Element Content In Cosmetics; Guidance To Come? In a study recently published in the Journal of Cosmetic Science, FDA assessed levels of seven trace contaminants in 150 cosmetic products on the market. The agency says the survey will help it to "make appropriate decisions regarding elemental contaminants in cosmetics."
"The Rose Sheet" August 15 2014 9:50 AM

Without User Fees, FDA's Monograph Review Process Lacks Manpower FDA's work on time-and-extent applications and monograph updates, unlike its work in evaluating NDAs for some OTC drugs and for Rx products, is not supported by user fees. The difference shows in the stalled process for approving new monograph ingredients, says the acting head of FDA's OTC drugs office.
"The Rose Sheet" August 18 2014 12:00 AM

Fast-Growing *Glop & Glam* To Cuddle With *SoCozy* In Children's Hair Care While recent sales declines in children's hair care speak to challenges in the segment, brands such as Glop & Glam have carved out successful niches - particularly in the salon channel. Newcomer SoCozy hopes to make a similar impression with its line of kids' hair-care products with "a cool urban flair."
"The Rose Sheet" August 18 2014 12:00 AM

Regulatory/Legislative

Dr. Bronner's Draws FDA Warning For Coconut Oil Disease Claim According to FDA, (b) (6) Magic "All-One!" organic virgin coconut oil is an unapproved new drug based on a labeling claim indicating cholesterol benefits and, by extension, reduced coronary heart disease risk.
"The Rose Sheet" August 18 2014 12:00 AM

N.Y. Sen. Gillibrand Seeks Federal Action On Personal-Care Microbeads A federal interagency task force should include microbeads and microplastics from personal-care products on its list of Great Lakes contaminants, New York Senator (b) (6) asserts in a letter to EPA Administrator Gina McCarthy. The move would generate more in-depth study of the ingredients and allow for "the development of proper remediation."
"The Rose Sheet" August 18 2014 12:00 AM

New Products

New Products In Brief: *Hue For Every Man*, New *Colgate* Mouthwash; *Vita Coco* Oil; More Luxury grooming line Hue For Every Man launches, aimed at the multicultural market; Colgate Total Lasting White Mouthwash debuts; Vita Coco expands into coconut oil for culinary and beauty purposes. More new products.
"The Rose Sheet" August 18 2014 12:00 AM

Marketing/Advertising

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

In Brief

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

Trademarks

Weekly Trademark Review Aug 12, 2014 [Class 3 (Cosmetics and Cleaning Preps) compiled by "The Rose Sheet" from Official Gazette of the U.S. Patent and Trademark Office] Product Name Trademark No./ [Serial No.] Company Filed Date [Published] Class Nos.
"The Rose Sheet" August 18 2014 12:01 AM

From: The Rose Sheet
To: Katz, Linda
Subject: California DTSC's Draft Work Plan Includes Personal Care, But Few Surprises
Date: Thursday, September 18, 2014 4:54:09 PM

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LATEST NEWS

California DTSC's Draft Work Plan Includes Personal Care, But Few Surprises California's Department of Toxic Substances has identified "beauty, personal care and hygiene" as one of seven product categories that could yield next-round priority product selections under the state's Safer Consumer Products regulations. PCPC's Associate General Counsel (b) (6) says there are no big surprises in the nomination or the candidate chemicals identified - including formaldehyde, lead and phthalates - and he welcomed the direction DTSC appears to be taking toward more active industry engagement over the next three years.

"The Rose Sheet" September 18 2014 3:55 PM