Fibromyalgia

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

Penicillin, shellfish

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.

Valacyclovir 500 mg daily

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

Probiotic, vitamin b complex, vitamin d, Alavert, tylenol

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	24-May-2019	
	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, please mark this box (Confidentiality Requested):	Yes	

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		
Override Auto Calculation Rule	No		
FDA Received Date	06-Jul-2019	CTU Received Date	06-Jul-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	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
Date the problem occurred	03-Jul-2019
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I had a Keratin treatment applied at Hair Today in Norriston in Pennsylvania and it caused severe eye and nasal watering.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	Cosmetic,Dietary Supplement or Food/Medicinal Food
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Keratin Hair Treatment
Name of the company that makes (or compounds) the product	
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar
Strength	If Other
NDC number	
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?	Doesn't Apply

Drug Therapy 1 of 1

Expiration date		
Lot number		
Dosage Form		
Quantity		If Other
Frequency		If Other
How was it taken or used		If Other
Date the person first started taking or using the product	02-Jul-2019	
Date the person stopped taking or using the product	02-Jul-2019	
Give best estimate of duration		

Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Keratin Treatment

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

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

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration 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)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	43 Year(s)
Date of Birth	
Weight	74.25 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check 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)

Asthma and allergies

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

Pollen, dust mites, mold and dog dander

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.

Fluticasone nasal spray and loratadine

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

Vitamin D3, Omega 3, Magnesium, Iron and multi

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
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)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	06-Jul-2019	
	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, please mark this box (Confidentiality Requested):	No	

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		
Override Auto Calculation Rule	No		
FDA Received Date	31-Jul-2019	CTU Received Date	31-Jul-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	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
Date the problem occurred	
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I am a hairstylist . I have had reactions which I believe where caused by Brazilian blowout. My doctors currently think that my inflamed liver has been a result of my inhalation of the formaldehyde fumes from this product

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes	
Primary?	Yes	
Type	Drug/Biologic	
This report is about		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout .smooth ritual . Uberliss. Keratin complex. Express	
Name of the company that makes (or compounds) the product	Brazilian blowout.Uberlis s. coppol	
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar	
Strength		If Other
NDC number		
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	

Drug Therapy 1 of 1

Expiration date		
Lot number		
Dosage Form		
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		
Give best estimate of duration		

Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

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

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration 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)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	47 Year(s)
Date of Birth	
Weight	61.2 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check 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)

Autoimmune hepatitis Nash

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

Penicillins Omnicef Tequiin Macrobid Mango Surgical adhesive

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

None

List all current prescription medications and medical devices being used.

Hydroxizine allergy med

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

Probiotic

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	31-Jul-2019	
	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, please mark this box (Confidentiality Requested):	Yes	

CTU No.: FDA-CDER-CTU-2019-100428 | Department: CFSAN | RCT No.: RCT-543048 | CTU Triage Date: 28-08-2019 | Total Page 5 2

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/15)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # US-JNJFOC-20190820522
UF/Importer Report #
FDA Use Only

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

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In Confidence
2. Age: ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s) or Date of Birth (e.g., 08 Feb 1925): (b) (6)
3. Sex: ☒ Female ☐ Male
4. Weight: ☐ 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 OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)
2. Outcome Attributed to Adverse Event (Check all that apply)
☐ Death Include date (dd-mmm-yyyy):
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization - initial or prolonged ☐ Congenital Anomaly/Birth Defects
☒ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy):
4. Date of this Report (dd-mmm-yyyy): 25-Aug-2019

5. Describe Event or Problem
This spontaneous report received from a patient concerned a female of unspecified age.
The patient's weight, height, and medical history were not reported.
The patient received OGX EVER STRAIGHTENING BRAZILIAN KERATIN
Continued

6. Relevant Tests/Laboratory Data, Including Dates

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

C. SUSPECT PRODUCT(S)

1. Name, Manufacturer/Compounder, Strength

#1 - Name and Strength	#1 - NDC # or Unique ID
OGX EVER Continued	
#1 - Manufacturer/Compounder	#1 - Lot#
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot#

2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
Concomitant Drugs Not Reported

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3. Dose	Frequency	Route Used
#1		Topical
#2		

4. Therapy Dates (If unknown give duration) from/to (or best estimate) (dd-mmm-yyyy)
#1
#2

5. Diagnosis for Use (Indication)
#1 UNKNOWN INDICATION
#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

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: JNJ Consumer US Cosmetic
Address: OCMS, 199 Grandview Road, Skillman, NJ
Continued
Email Address: ngami@its.jnj.com
Compounding Outsourcing Facility 503B? ☐ Yes

2. Phone Number: 732-754-2672

3. Report Source (Check all that apply)
☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (dd-mmm-yyyy): 15-Aug-2019

5. NDA # ____ ANDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
GTC ☐ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☒ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☐ 15-day ☐ Follow-up # ____

8. Manufacturer Report Number: US-JNJFOC-20190820522

8. Adverse Event Term(s)
1) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical
Continued

E. INITIAL REPORTER

1. Name and Address
Continued
Last Name: (b) (6) First Name: (b) (6)
Address: (b) (6)
City: (b) (6) State/Province/Region:
Country: USA ZIP/Postal Code: (b) (6)
Phone #: Email: (b) (6)

2. Health Professional? ☐ Yes ☒ No
3. Occupation: Patient
4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☐ Unk

B. ADVERSE EVENT OR PRODUCT PROBLEM

B.5 Describe Event or Problem (Cont...)

THERAPY CONDITIONER UNSPECIFIED (shampoo, topical, batch number not reported) dose, frequency, and therapy dates not reported, for unknown indication. No concomitant medications were reported. On an unspecified date, the patient got sick due to formaldehyde poisoning of her whole body. She lost her hair and her teeth were removed due to the damage the product caused in her mouth and formaldehyde pockets were found in her gums which were not going away. The product ingredient issue was reported.
The action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER UNSPECIFIED was not reported.
The patient had not recovered from formaldehyde poisoning, hair loss and formaldehyde pockets in gums. The outcome for product ingredient issue was not reported.
This report was serious (Other Medically Important Condition).
This report was associated with a product quality complaint: 30001580043.

Company Remarks :

...

C. SUSPECT PRODUCT(S) (Cont...)

Seq No.	:1
C.1 Suspect Product	:OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER
C.9 Dechallenge	:2) N/A :3) N/A :4) N/A
C.10 Rechallenge	:2) N/A :3) N/A :4) N/A

E. INITIAL REPORTER (Cont...)

Email: totalonipper@gmail.com

G. ALL MANUFACTURERS

G.1 Contact Office : Name/Address (and Manufacturing Site for Devices)

United States of America
(Printing Unit)

G.8 Adverse Event Term(s)

1) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
2) hair loss (Application site alopecia (10059046), Application site alopecia (10059046))
3) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))
4) PRODUCT INGREDIENT ISSUE (Product ingredient issue (10071303), Product formulation issue (10069228))

CTU No.: FDA-CDER-CTU-2019-101858 | Department: CFSAN | RCT No.: RCT-549098 | CTU Triage Date: 02-09-2019 | Total Page s: 2

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/15)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # US-JNJFOC-20190820522
UF/Importer Report #
FDA Use Only

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

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In Confidence
2. Age: ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s) or Date of Birth (dd-mmm-yyyy): (b) (6)
3. Sex: ☒ Female ☐ Male
4. Weight: ☐ 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 OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

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)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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

4. Date of this Report (dd-mmm-yyyy): 27-Aug-2019

5. Describe Event or Problem
This spontaneous report received from a patient concerned a female of unspecified age.
The patient's weight, height, and medical history were not reported.
The patient received OGX EVER STRAIGHTENING BRAZILIAN KERATIN
Continued

6. Relevant Tests/Laboratory Data, Including Dates

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

C. SUSPECT PRODUCT(S)

1. Name, Manufacturer/Compounder, Strength

#1 - Name and Strength	#1 - NDC # or Unique ID
OGX EVER Continued	
#1 - Manufacturer/Compounder	#1 - Lot#
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot#

2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
Concomitant Drugs Not Reported

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3. Dose	Frequency	Route Used
#1		Topical
#2		

4. Therapy Dates (If unknown give duration) from/to (or best estimate) (dd-mmm-yyyy)
#1
#2

5. Diagnosis for Use (Indication)
#1 UNKNOWN INDICATION
#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

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: JNJ Consumer US Cosmetic
Address: OCMS 199 Grandview Road Skillman,NJ
Continued
Email Address: ngami@its.jnj.com

2. Phone Number: 732-754-2672

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other

Compounding Outsourcing Facility 503B? ☐ Yes

4. Date Received by Manufacturer (dd-mmm-yyyy): 15-Aug-2019

5. NDA # ANDA # IND # BLA # PMA/510(k) #

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☒ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☐ 15-day ☐ Follow-up # ___

Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC ☐ Yes

9. Manufacturer Report Number: US-JNJFOC-20190820522

8. Adverse Event Term(s)
1) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical
Continued

E. INITIAL REPORTER

1. Name and Address Continued
Last Name: (b) (6) First Name: (b) (6)
Address: (b) (6)
City: (b) (6) State/Province/Region
Country: USA ZIP/Postal Code: (b) (6)
Phone # Email: (b) (6)

2. Health Professional? ☐ Yes ☒ No

3. Occupation: Patient

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☐ Unk

CTU No.: FDA-CDER-CTU-2019-101858 | Department: CFSAN | RCT No.: RCT-549098 | CTU Triage Date: 02-09-2019 | Total Page s:2

B. ADVERSE EVENT OR PRODUCT PROBLEM

B.5 Describe Event or Problem (Cont...)

THERAPY CONDITIONER UNSPECIFIED (shampoo, topical, batch number not reported) dose, frequency, and therapy dates not reported, for unknown indication. No concomitant medications were reported. On an unspecified date, the patient got sick due to formaldehyde poisoning of her whole body. She lost her hair and her teeth were removed due to the damage the product caused in her mouth and formaldehyde pockets were found in her gums which were not going away. The product ingredient issue was reported. The product label had improper directions (product label issue)
The action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER UNSPECIFIED was not reported.
The patient had not recovered from formaldehyde poisoning, hair loss and formaldehyde pockets in gums. The outcome for product ingredient issue and product label issue was not reported.
This report was serious (Other Medically Important Condition).
This report was associated with a product quality complaint: 30001580043.

Version created to amend previously reported information on 15-AUG-2019. Upon review, the following information was amended: event details (product label issue).

Company Remarks :

...

C. SUSPECT PRODUCT(S) (Cont...)

Seq No.	:1
C.1 Suspect Product	:OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER
C.9 Dechallenge	:2) N/A :3) N/A :4) N/A :5) N/A
C.10 Rechallenge	:2) N/A :3) N/A :4) N/A :5) N/A

E. INITIAL REPORTER (Cont...)

Email: totalonipper@gmail.com

G. ALL MANUFACTURERS

G.1 Contact Office : Name/Address (and Manufacturing Site for Devices)

United States of America
(Printing Unit)

G.8 Adverse Event Term(s)

1) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
2) hair loss (Application site alopecia (10059046), Application site alopecia (10059046))
3) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018290))
4) PRODUCT INGREDIENT ISSUE (Product ingredient issue (10071303), Product formulation issue (10069228))
5) IMPROPER DIRECTIONS (PRODUCT LABEL ISSUE) (Product label issue (10069289), Product label issue (10069289))

CTU No.: FDA-CDER-CTU-2019-106002 | Department: CFSAN | RCT No.: RCT-570785 | CTU Triage Date: 13-09-2019 | Total Page s: 2

Form Approved: OMB No. 0910-0291, Expires: 9/30/2016
See PRA statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/15)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # US-JNJFOC-20190820522
UF/Importer Report #
FDA Use Only

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

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In Confidence
2. Age: ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s) or Date of Birth (e.g., 08 Feb 1925): (b) (6)
3. Sex: ☒ Female ☐ Male
4. Weight: ☐ 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 OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

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)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy):
4. Date of this Report (dd-mmm-yyyy): 08-Sep-2019

5. Describe Event or Problem
This spontaneous report received from a patient concerned a female of unspecified age.
The patient's weight, height, and medical history were not reported.
The patient received OGX EVER STRAIGHTENING BRAZILIAN KERATIN
Continued

6. Relevant Tests/Laboratory Data, Including Dates

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

C. SUSPECT PRODUCT(S)

1. Name, Manufacturer/Compounder, Strength

#1 - Name and Strength	#1 - NDC # or Unique ID
OGX EVER Continued	
#1 - Manufacturer/Compounder	#1 - Lot#
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot#

2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
Concomitant Drugs Not Reported

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3. Dose	Frequency	Route Used
#1		Topical
#2		

4. Therapy Dates (If unknown give duration) from/to (or best estimate)) (dd-mmm-yyyy)
#1
#2

5. Diagnosis for Use (Indication)
#1 UNKNOWN INDICATION
#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

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: JNJ Consumer US Cosmetic
Address: OCMS 199 Grandview Road Skillman,NJ Continued
Email Address: ngami@its.jnj.com
Compounding Outsourcing Facility 503B? ☐ Yes

2. Phone Number: 732-754-2672

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other

4. Date Received by Manufacturer (dd-mmm-yyyy): 15-Aug-2019

5. NDA #
ANDA #
IND #
BLA #
PMA/510(k) #

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☒ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☒ Follow-up # 2

Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC ☐ Yes

8. Manufacturer Report Number: US-JNJFOC-20190820522

9. Adverse Event Term(s)
1) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical Continued

E. INITIAL REPORTER

1. Name and Address Continued
Last Name: (b) (6) First Name: (b) (6)
Address: (b) (6)
City: (b) (6) State/Province/Region:
Country: USA ZIP/Postal Code: (b) (6)
Phone #: Email: (b) (6)

2. Health Professional? ☐ Yes ☒ No
3. Occupation: Patient
4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☐ Unk

B. ADVERSE EVENT OR PRODUCT PROBLEM

B.5 Describe Event or Problem (Cont...)

THERAPY CONDITIONER UNSPECIFIED (shampoo, topical, batch number not reported) dose, frequency, and therapy dates not reported, for unknown indication. No concomitant medications were reported. On an unspecified date, the patient got sick due to formaldehyde poisoning of her whole body. She lost her hair and her teeth were removed due to the damage the product caused in her mouth and formaldehyde pockets were found in her gums which were not going away.
The action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER UNSPECIFIED was not reported.
The patient had not recovered from formaldehyde poisoning, hair loss and formaldehyde pockets in gums.
This report was serious (Other Medically Important Condition).

Version created to amend previously reported information on 15-AUG-2019. Upon review, the following information was amended: event details (product label issue).

Additional information was received from patient on 15-AUG-2019. Upon review, the following information was amended: event of product ingredient issue and product label issue removed.

Company Remarks :

...

C. SUSPECT PRODUCT(S) (Cont...)

Seq No.	:1
C.1 Suspect Product	:OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER
C.9 Dechallenge	:2) N/A :3) N/A
C.10 Rechallenge	:2) N/A :3) N/A

E. INITIAL REPORTER (Cont...)

Email: totalonipper@gmail.com

G. ALL MANUFACTURERS

G.1 Contact Office : Name/Address (and Manufacturing Site for Devices)

United States of America
(Printing Unit)

G.8 Adverse Event Term(s)

1) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
2) hair loss (Application site alopecia (10059046), Application site alopecia (10059046))
3) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))

CTU No.: FDA-CDER-CTU-2019-108138 | Department: CFSAN | RCT No.: RCT-578831 | CTU Triage Date: 18-09-2019 | Total Pages: 2

Form Approved. OMB No. 0910 0291. Expires: 9/30/2018
See PRA statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/15)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #: US-JNJFOC-20190820522
UF/Importer Report #:
FDA Use Only

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

A. PATIENT INFORMATION

1. Patient Identifier	2. Age	3. Sex	4. Weight
(b) (6) In Confidence	☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s) or Date of Birth (e.g., 03 Feb 1926): (b) (6)	☒ Female ☐ Male	☐ 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 OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

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

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

4. Date of this Report (dd-mmm-yyyy): 14-Sep-2019

5. Describe Event or Problem
This spontaneous report received from a patient concerned a female of unspecified age.
The patient's weight, height, and medical history were not reported.
The patient received OGX EVER STRAIGHTENING BRAZILIAN KERATIN
Continued

6. Relevant Tests/Laboratory Data, Including Dates

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

C. SUSPECT PRODUCT(S)

1. Name, Manufacturer/Compounder, Strength

#1 - Name and Strength	#1 - NDC # or Unique ID
OGX EVER Continued	
#1 - Manufacturer/Compounder	#1 - Lot#
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot#

2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
Concomitant Drugs Not Reported

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3. Dose	Frequency	Route Used
#1		Topical
#2		

4. Therapy Dates (If unknown give duration) from/to (or best estimate)) (dd-mmm-yyyy)
#1
#2

5. Diagnosis for Use (Indication)
#1 UNKNOWN INDICATION
#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

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: JNJ Consumer US Cosmetic
Address: OCMS, 199 Grandview Road, Skillman, NJ
Continued
Email Address: ngami@its.jnj.com
Compounding Outsourcing Facility 503B? ☐ Yes

2. Phone Number: 732-754-2672

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer (dd-mmm-yyyy): 15-Aug-2019

5. NDA #
ANDA #
IND #
BLA #
PMA/510(k) #

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☒ 30-day
☐ 7-day ☐ Periodic
☐ 10 day ☐ Initial
☐ 15-day ☒ Follow-up # 2

Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC ☐ Yes

9. Manufacturer Report Number: US-JNJFOC-20190820522

8. Adverse Event Term(s)
1) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical
Continued

E. INITIAL REPORTER

1. Name and Address
Continued
Last Name: (b) (6) First Name: (b) (6)
Address: (b) (6)
City: (b) (6) State/Province/Region: (b) (6)
Country: USA ZIP/Postal Code:
Phone #: Email: (b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	Patient	☐ Yes ☐ No ☐ Unk

CTU No.: FDA-CDER-CTU-2019-108138 | Department: CFSAN | RCT No.: RCT-578831 | CTU Triage Date: 18-09-2019 | Total Pages: 2

Continuation Sheet for FDA-3500A Form Page 2 of 2

Mfr. Report # : US-JNJFOC-20190820522

Date of This Report : 14-Sep-2019

B. ADVERSE EVENT OR PRODUCT PROBLEM

B.5 Describe Event or Problem (Cont...)

THERAPY CONDITIONER UNSPECIFIED (shampoo, topical, batch number not reported) dose, frequency, and therapy dates not reported, for unknown indication. No concomitant medications were reported. On an unspecified date, the patient got sick due to formaldehyde poisoning of her whole body. She lost her hair and her teeth were removed due to the damage the product caused in her mouth and formaldehyde pockets were found in her gums which were not going away.
The action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER UNSPECIFIED was not reported.
The patient had not recovered from formaldehyde poisoning, hair loss and formaldehyde pockets in gums.
This report was serious (Other Medically Important Condition).

Version created to amend previously reported information on 15-AUG-2019. Upon review, the following information was amended: event details (product label issue).

Additional information was received from patient on 15-AUG-2019. Upon review, the following information was amended: event of product ingredient issue and product label issue removed.

Additional information was received on 15-AUG-2019.
It has been determined that this case is a duplicate of Manufacturer Report Number 20180719747. This case (Manufacturer Report Number 20190820522) will be deleted. All relevant information regarding this case will be submitted under Manufacturer Report Number 20180719747.

Company Remarks :

...

C. SUSPECT PRODUCT(S) (Cont...)

Seq No.	:1
C.1 Suspect Product	:OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY CONDITIONER
C.9 Dechallenge	:2) N/A :3) N/A
C.10 Rechallenge	:2) N/A :3) N/A

E. INITIAL REPORTER (Cont...)

Email: totalonipper@gmail.com

G. ALL MANUFACTURERS

G.1 Contact Office : Name/Address (and Manufacturing Site for Devices)

United States of America
(Printing Unit)

G.8 Adverse Event Term(s)

1) FORMALDEHYDE POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
2) hair loss (Application site alopecia (10059046), Application site alopecia (10059046))
3) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))

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		
Override Auto Calculation Rule	No		
FDA Received Date	19-Oct-2019	CTU Received Date	19-Oct-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(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
Date the problem occurred	19-Oct-2019
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Was in a salon where another client was receiving a keratin hair straightening treatment. The fumes released were toxic, causing stinging eyes, runny nose and respiratory distress. There was no warning this procedure was being performed. And there was no way to escape it without going outside, which is impossible in cold weather with wet hair. This is the second time I have encountered this in a salon in the past three years, and I have respiratory issues, so do not take this lightly. I understand OSHA may have ventilation regulations but the salons do not comply. And ALL customers and workers in the salon - not just the ones who opt to receive or perform this treatment - are at risk. This product should be banned.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	Cosmetic,Dietary Supplement or Food/Medicinal Food
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	keratin hair straightening treatment - brand unknown
Name of the company that makes (or compounds) the product	
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar
Strength	If Other
NDC number	
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?	

Drug Therapy 1 of 1

Expiration date	
Lot number	
Dosage Form	
Quantity	If Other
Frequency	If Other
How was it taken or used	If Other
Date the person first started taking or using the product	
Date the person stopped taking or using the product	
Give best estimate of duration	

Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

cosmetic

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

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

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration 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)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	61 Year(s)
Date of Birth	
Weight	71.1 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check 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)

dust mites

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.

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	19-Oct-2019	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

[Close]

FACTS Interface

FACTS Complaint #129433 (CAERS #163098)			
Complaint Date	11/23/2012	**Complaint Source**	Consumer
Accomplishing District	DEN-DO	**Complaint Status**	Archived
How Received	Telephone		

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

Complaint / Injury

Complaint Description

(b) (6), stated that two years ago she received a "Brazilian Blowout," which is a hair-straightening treatment, at a salon. Following the treatment, she experienced a rash on her arms and stomach. Upon seeing her physician, he stated that it could be a photosynthetic reaction on the product from the Sun, however, the physician did not know why it was on her arms and stomach and not on her scalp. She treated the rash with OTC cortizone and sustained the rash for over a week. On 11/19/12 (b) (6) decided that she wanted to get a hair straightening treatment. She went to (b) (4) where she states that the stylist stated the product was "all natural and contains only Brazilian honey and protein." The product is a "Brazilian keratin treatment." Almost immediately after receiving the treatment while driving home (b) (6) stated that the "chemical smell" on her hair was strong and her eyes started burning. She stated that the irritation was moderate to severe. When she got home, she called Zing Salon to find out more information about the product. She stated that the owner of the salon was very "nasty" with her and would not tell her the name of the product or the ingredients. The owner only told her that it was imported from Brazil and the conversation ended. (b) (6) stated that she immediately washed the product out of her hair. When her eyes continued burning through Wednesday 11/21/12, she went to see a nurse practitioner at Northwest Family Medicine. She does not remember the name of the practitioner. She stated that the practitioner advised her to use eye drops when necessary. On 11/23/12, (b) (6) stated that her eyes no longer burn.

Adverse Event Result	None
Adverse Event Date	11/19/2012
Notify EIO/EMOPS?	No
Notification Date	
Attended Health Professional?	Yes
Required Hospitalization?	No
Emergency Room/ Outpatient Visit?	No
Reported Complaint To?	Other
Need Additional/ FDA Contact?	Unknown

Remarks

(b) (6) experienced moderate to severe eye burning and irritation (b) (6) reported the complaint to the Colorado Barber and Cosmetology Board. They instructed her to report her complaint to the FDA and the Boulder County Department of Health. (b) (6) stated that the Boulder-COH was not open on 11/23/12 when she tried contacting them. She stated that she will try to contact them again next week.

Complaint Symptoms

Symptom Name	Duration	Remarks
Eye irritation	2 Day(s)	

Health Care Professional

Health Care Type	Provider Name	Address	Phone	Occupation	Stay Dates

Health Care Professional	Northwest Family Medicine	500 Discovery Parkway Louisville CO 80027 US	(303) 425-9581		

Product and Labeling

Brand Name	Unknown		
Product Name	Honey Brazilian Keratin Treatment		
FDA Product Code	53EY03	**Qty/Unit**	
UPC Code		**Package**	
Exp/Use By Date		**Lot/Serial**	
Product Used?	Yes	**Purchase Date**	
Date Used?	11/19/2012	**Amount Consumed/Used**	
Amount Remained		**Date Discontinued**	11/19/2012
Country of Origin		**Imported Product?**	No
Retailer Name	Zing Hair Salon	**Label Remarks**	

Manufacturer/Distributor

There is no firm information listed for this consumer complaint report.

Initial Evaluation / Initial Disposition

Initial Evaluation	Insuffici. Info. unable to evaluate	**Initial Disposition**	Closed w/o further Investigation
Disposition Date	03/06/2013		

Remarks

Firm unknown because brand name of product is unknown.

Problem Keyword	Problem Keyword Details
Reaction	rash on her arms and stomach

Cosmetic

Cosmetic ID #23801

DOB	(b) (6)	**Age**	42
Gender	Female	**Race**	
Application Place	Salon/SPA	**Reason for Use**	Hair Preparations (Non-Coloring)
Application Site	Hair	**Other Products?**	
Directions			
Directions Followed?		**Product Duration**	Day(s)
Frequency of Use		**Reaction Site**	Face
Product Use in Off-Label Manner?		**Off-Label Manner Desc**	
Warning Statement on Label?		**Warning Statements?**	
Preexisting Conditions?		**Treatment**	Physician
Current Status	Clear		

Medical Diagnosis	Medical Treatment
Eye irritation/burning	OTC eye drops

Remarks

(b) (6) was treated by a nurse practitioner. She stated that she does not remember the practitioner's name.

Adverse Events

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

[Close]

March 13, 2013

To Whom It May Concern:

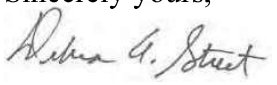
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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 # 163098.

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

Sincerely yours,



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

Enclosure

1635941

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

Internet Submission - Page 1/2

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

FDA USE ONLY
Triage unit sequence # 506132

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	24 Years	☑ Female ☐ Male	125 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
03/08/2013	03/15/2013

5. Describe Event, Problem or Product Use Error

I am a hairstylist and have been using the Coppola Keratin Complex Smoothing Treatment for three years. One of my co-workers gets nosebleeds whenever the service is done in the salon, another gets headaches and coughs, and my clients' eyes often burn/tear/itch. I have been hearing mixed opinions when it comes to whether or not the treatment is safe. My understanding is that the product itself does not contain formaldehyde; it contains aldehyde, a natural product. The company is therefore able to market the product as 'formaldehyde free.' However, once it is heated -which it needs to be in order for the product to work-, the aldehyde

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MAR 19 2013

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Coppola Keratin Complex
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

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

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

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Coppola Keratin Complex Smoothing System
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)

'13 MR 19

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

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

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

506132

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

B5. Describe event or problem continued

changes to formaldehyde, a known carcinogen. Last week I received news that a stylist in the local area who specializes in the treatment was diagnosed with lung cancer. This makes me very concerned. My questions: is the keratin treatment safe? Is it FDA regulated? Does it omit formaldehyde and if so, is it enough to be concerned about? Is it linked to cancer? Is it dangerous to just the client or stylist, or is it a potential threat to everyone in the salon?

March 26, 2013

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 163594.

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

Sincerely yours,

Debra G. Street

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

Enclosure

1635941

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

Internet Submission - Page 1/2

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

FDA USE ONLY
Triage unit sequence #: 506132

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	24 Years	☑ Female ☐ Male	125 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
03/08/2013	03/15/2013

5. Describe Event, Problem or Product Use Error

I am a hairstylist and have been using the Coppola Keratin Complex Smoothing Treatment for three years. One of my co-workers gets nosebleeds whenever the service is done in the salon, another gets headaches and coughs, and my clients' eyes often burn/tear/itch. I have been hearing mixed opinions when it comes to whether or not the treatment is safe. My understanding is that the product itself does not contain formaldehyde; it contains aldehyde, a natural product. The company is therefore able to market the product as 'formaldehyde free.' However, once it is heated -which it needs to be in order for the product to work-, the aldehyde

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MAR 19 2013

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Coppola Keratin Complex
#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: Coppola Keratin Complex Smoothing System
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)

'13 MR 29

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

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

506132

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

B5. Describe event or problem continued

changes to formaldehyde, a known carcinogen. Last week I received news that a stylist in the local area who specializes in the treatment was diagnosed with lung cancer. This makes me very concerned. My questions: is the keratin treatment safe? Is it FDA regulated? Does it omit formaldehyde and if so, is it enough to be concerned about? Is it linked to cancer? Is it dangerous to just the client or stylist, or is it a potential threat to everyone in the salon?

March 26, 2013

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

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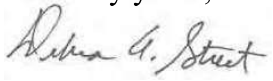
We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 163619.

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

Sincerely yours,



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

Enclosure

1035941

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

Internet Submission - Page 1/2

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

FDA USE ONLY
Triage unit sequence # 506132

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event, or Date of Birth: 24 Years	3. Sex: ☑ Female ☐ Male	4. Weight: 125 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
03/08/2013	03/15/2013

5. Describe Event, Problem or Product Use Error

I am a hairstylist and have been using the Coppola Keratin Complex Smoothing Treatment for three years. One of my co-workers gets nosebleeds whenever the service is done in the salon, another gets headaches and coughs, and my clients' eyes often burn/tear/itch. I have been hearing mixed opinions when it comes to whether or not the treatment is safe. My understanding is that the product itself does not contain formaldehyde; it contains aldehyde, a natural product. The company is therefore able to market the product as 'formaldehyde free.' However, once it is heated -which it needs to be in order for the product to work-, the aldehyde

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MAR 19 2013

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Coppola Keratin Complex
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

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

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

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

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Coppola Keratin Complex Smoothing System
2. Common Device Name
3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # (b) (6)
Email (b) (6)

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

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

'13 MR 19

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

506132

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

B5. Describe event or problem continued

changes to formaldehyde, a known carcinogen. Last week I received news that a stylist in the local area who specializes in the treatment was diagnosed with lung cancer. This makes me very concerned. My questions: is the keratin treatment safe? Is it FDA regulated? Does it omit formaldehyde and if so, is it enough to be concerned about? Is it linked to cancer? Is it dangerous to just the client or stylist, or is it a potential threat to everyone in the salon?

March 26, 2013

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

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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,

Debra G. Street

Debra Street
Chief
Emergency Response and Surveillance Branch
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

Internet Submission - Page 1

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

FDA USE ONLY
Triage unit sequence # 5079662

07SAN 164187

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) in confidence	(b) (6) 64 Years	☑ Female ☐ Male	164 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: 03/17/2012 (mm/dd/yyyy) ☑ Disability or Permanent Damage
☑ Life-threatening ☑ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
03/17/2012	04/03/2013

5. Describe Event, Problem or Product Use Error

A beautician who worked at Shear Reflections in Mentor, Ohio gave me a Global Keratin treatment. I told her I had a permanent in my hair at the time and she told me that it was safe to apply the Keratin treatment over top of the permanent. She applied the treatment to the hair and then used a 450 degree flat iron to straighten the hair. For days I felt deep heat penetrations to my scalp. She told me to come back in 3 days to have it rinsed out and blow dried. The first time she did my hair, it was beautiful with lots of body and shine, but when I went back for the rinse out, the hair was completely damaged- in other words it was fried

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APR - 4 2013

More

6. Relevant Tests/Laboratory Data, Including Dates

The Cleveland Clinic tells me that the hair will eventually grow back, but I don't believe it. My hair is so badly damaged. The product used is formaldehyde and the doctor get hesitant when she heard this chemical was used.

More

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

I don't smoke or drink.

More

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 Global Keratin Unknown Proline
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 03/17/2012 -- 04/03/2013 (one year)
#2 -- --

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

4. Diagnosis or Reason for Use (Indication)
#1 Used to keep hair conditioned
#2

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

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 26998	#1	1365mt14
#2 1365mt14	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Global Keratin Straightener
2. Common Device Name: GK Keratin
3. Manufacturer Name, City and State: Global Keratin Corp, Ft Lauderdale, Fl 33312

4. Model #	Lot # 26998	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)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # 4409981062 E-mail blackwell3@windstream.net

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

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

'13 APR

507962

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

B5. Describe event or problem continued

with no life whatsoever. I began having terrible headaches and the hair began falling out. I went back to the owner, Caroline, three times and each time she told me that my hair would be okay. She said after 3 to 6 months, the keratin would be out of the hair. In the meantime I went completely bald in the top of my head - from ear to ear. I contacted the company that made the product and they claimed that she put too much heat on my head. I went to other beauty shops for treatments but nothing worked for the damage done to my hair. My last resort was the Cleveland Clinic. They have reports of many women having damage from using these products and in all cases hair loss is the major issue. I have been wearing wigs for one year because of the damage to my head. I feel a class action lawsuit needs to done in this situation.

June 06, 2013

Global Keratin Corp
5555 Ravenswood Road 16b
Fort Lauderdale, Florida 33312

To Whom It May Concern:

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

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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,

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

Enclosure

164818

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

Internet Submission - Page 1 of 3

Form Approved: OMB No. 0910-0291 Expires: 10/31/2007 See OMB Statement on reverse.

FDA USE ONLY

Triage unit sequence # 5098167

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	38 Years	☑ Female ☐ Male	116 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
04/20/2013	04/20/2013

5. Describe Event, Problem or Product Use Error

I used Nailtiques Formula 2 Nail Hardener and experiences a severe reaction. My fingernails were in so much pain and the nail traveled up my fingers. I believe the product contained an higher level of formaldehyde than it should have. I have never had any reaction to any nail product in my life and I have probably used hundred of different polishes and acrylic nail products. This cannot be normal. I did not see anything on how to relieve this problem on any website

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

No allergies.

More

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 Nailtiques Formula 2

#2

2.	Dose or Amount	Frequency	Route
#1	one coat	per day	
#2			

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

#1 once per day 04/15/2013 -- 04/20/2013

#2 --

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (indication)

#1 nail hardener for thin nails

#2

6. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Nailtiques

2. Common Device Name: CTU

3. Manufacturer Name, City and State: Nailtiques Miami, FL

APR 22 2013

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)

More

'13APR

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

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

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

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

May 06, 2013

Nailtiques
10315 102nd Terrace
Sebastian, Florida 32958-7823

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 # 164818.

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

Sincerely yours,

Debra G. Street

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

Enclosure

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

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

Page ____ of ____

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
Sister In confidence	28 Hispanic	☐ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/19/2013	04/26/2013

5. Describe Event, Problem or Product Use Error

Process was done at a salon- Belleza Latina- on 04/17/2013. Consumer had an allergic reaction- itchy scalp, rash, blisters along hair line. Formaldehyde is a reported ingredient. Specific product information- exact brand name, manufacturer, lot number- was unavailable.

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

Amazon Keratin

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

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

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

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)

(b) (6)

Phone #	E-mail
(b) (6) 9	

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

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

PLEASE TYPE OR USE BLACK INK

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

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

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

Page ____ of ____

FDA USE ONLY

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6) In confidence
2. **Age at Time of Event, or Date of Birth** 63 Caucasian
3. **Sex** ☐ Female ☐ Male
4. **Weight** _____ lb or _____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. **Date of Event** *(mm/dd/yyyy)* 06/05/2013
4. **Date of this Report** *(mm/dd/yyyy)* 06/10/2013

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

Consumer used product on 06/05/2013 and experienced burning eyes and burning skin. She went to the ER on 06/08/2013 and received an anti-inflammatory shot. She contacted the manufacturer who said the product was formaldehyde free. She thinks that it has formaldehyde that is released by heat. She reports that she followed application instructions. She didn't do a patch test as this was not indicated in the directions.

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

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

Mark Anthony Frizz Free Keratin Treatment

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

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 #** not available
7. **Expiration Date**
9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**
2. **Common Device Name**
3. **Manufacturer Name, City and State**
4. **Model #** **Lot #** **Catalog #** **Expiration Date** *(mm/dd/yyyy)* **Serial #** **Other #**
5. **Operator of Device** ☐ Health Professional ☐ Lay User/Patient ☐ Other: _____
6. **If Implanted, Give Date** *(mm/dd/yyyy)*
7. **If Explanted, Give Date** *(mm/dd/yyyy)*
8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?** ☐ Yes ☐ No
9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. **Name and Address**
(b) (6)

Phone # **E-mail**

2. **Health Professional?** ☐ Yes ☐ No
3. **Occupation**
4. **Also Reported to** ☐ Manufacturer User ☐ Facility ☐ Distributor/Importer
5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box** ☐

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

166420-002

MARC ANTHONY®
TRUE PROFESSIONAL

July 24, 2013

Department of Health & Human Services
CFSAN / CAERS Staff
(HFS-11)
5100 Paint Branch Parkway
College Park, MD 20740

Ref: CAERS # 166420

To Whom It May Concern:

In response to your letter dated June 11, 2013 (copy attached) and the Form FDA 3500 (copy attached) the product in question is the Marc Anthony Bye Bye Frizz Keratin Smoothing Treatment.

Please be advised that this product is formulated without formaldehyde or compounds that release formaldehyde and as such the irritation experienced by this consumer could not have been caused by the release of any formaldehyde from this product. This is the only complaint we have received on this product to date.

The product has been on the market since 2011 and we have not received any complaints other than the one in question today. During the development of this product our contract manufacturer, Zotos International Inc., has confirmed that no issues were noted while testing.

If you require further information regarding this case please contact us.

Regards,

Alexander Servinis, BAS, CGA
General Manager
Marc Anthony Cosmetics Inc.

Tel: 905-530-2500 ext. 231
Toll Free (CA & USA): 1-888-295-8856
Fax: 905-530-2508
Email: alex@marcanthony.com

'13JL2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

June 11, 2013

COPY

Mark Anthony
190 Pippin Road
Concord, Ontario
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), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 166420.

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

Sincerely yours,

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

Enclosure

U.S. Department of Health and Human Services

MEDWATCH

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

Page ____ of ____

FDA USE ONLY

Triage unit sequence # 3183

166420

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
[redacted] In confidence	63 Caucasian	[X] Female [ ] Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/05/2013	06/10/2013

5. Describe Event, Problem or Product Use Error

Consumer used product on 06/05/2013 and experienced burning eyes and burning skin. She went to the ER on 06/08/2013 and received an anti-inflammatory shot. She contacted the manufacturer who said the product was formaldehyde free. She thinks that it has formaldehyde that is released by heat. She reports that she followed application instructions. She didn't do a patch test as this was not indicated in the directions.

COPY

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

Mark Anthony Frizz Free Keratin Treatment

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

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

6. Lot # not available

7. Expiration Date

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

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

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. Name and Address
[redacted]

Phone # | E-mail

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

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

PLEASE TYPE OR USE BLACK INK

June 11, 2013

Mark Anthony
190 Pippin Road
Concord, Ontario
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), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 166420.

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

Sincerely yours,

Debra G. Street

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

Enclosure

[Close]

FACTS Interface

FACTS Complaint #122631 (CAERS #166590)			
Complaint Date	10/03/2011	**Complaint Source**	Consumer
Accomplishing District	FLA-DO	**Complaint Status**	Archived
How Received	Telephone		

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

Complaint / Injury		
Complaint Description Complainant stated she had her hair treated with Coppola Keratin Smoothing Therapy Complex by her hairdresser. She stated she started losing her hair the next day and to date has lost 60% of her hair. She has seen a doctor who did blood tests and stated she is healthy and the hair loss is probably due to the product. She has looked on the internet and seen several other references to this problem.	**Adverse Event Result**	Non-serious Injuries/ Illness
	Adverse Event Date	05/2011
	Notify EIO/EMOPS?	Yes
	Notification Date	10/03/2011
	Attended Health Professional?	Yes
	Required Hospitalization?	No
	Emergency Room/ Outpatient Visit?	No
	Reported Complaint To?	
	Need Additional/ FDA Contact?	
Remarks Hair loss		

Complaint Symptoms		
Symptom Name	**Duration**	**Remarks**
Balding	null null	Still losing up to 60% total hair loss so far

Health Care Professional					
Health Care Type	**Provider Name**	**Address**	**Phone**	**Occupation**	**Stay Dates**
(b) (4)					

Product and Labeling			
Brand Name	Coppola		
Product Name	Keratin Smoothing Therapy		
FDA Product Code	53ED03	**Qty/Unit**	
UPC Code		**Package**	
Exp/Use By Date		**Lot/Serial**	
Product Used?	Yes	**Purchase Date**	
Date Used?	07/2011	**Amount Consumed/Used**	
Amount Remained		**Date Discontinued**	
Country of Origin		**Imported Product?**	No
Retailer Name	Tangles Hair Salon	**Label Remarks** Had put on by hairdresser	

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3008765426	Keratonics 4377 NW 124th Ave Coral Springs FL 33065	FLA-DO	Manufacturer

Initial Evaluation / Initial Disposition

Initial Evaluation	FDA Action Indicated	**Initial Disposition**	Referred to Other FDA District
Disposition Date	10/07/2011		

Remarks

60 % hair loss would not allow NWE-DO to put in adverse events greyed out?

Problem Keyword	Problem Keyword Details
Other	60% Hair Loss

Cosmetic

Cosmetic ID #21399

DOB		**Age**	
Gender	Female	**Race**	
Application Place	Salon/SPA	**Reason for Use**	Hair Preparations (Non-Coloring)
Application Site	Hair	**Other Products?**	
Directions			
Directions Followed?		**Product Duration**	
Frequency of Use		**Reaction Site**	Scalp
Product Use in Off-Label Manner?		**Off-Label Manner Desc**	
Warning Statement on Label?		**Warning Statements?**	
Preexisting Conditions?		**Treatment**	
Current Status			
Medical Diagnosis		**Medical Treatment**	
Remarks			

Adverse Events

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

[Close]

June 28, 2013

Keratonics
4377 NW 124th Ave
Coral Springs, Florida 33065

To Whom It May Concern:

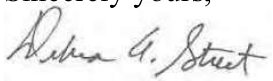
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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 # 166590.

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

Sincerely yours,



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

Enclosure

875NE 166682

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

(Internet) Submission - Page 1/2

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

FDA USE ONLY
Triage unit sequence # 515388

A. PATIENT INFORMATION

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

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
11/03/2012	06/17/2013

5. Describe Event, Problem or Product Use Error

On 03/Nov/2012, I decided to get a keratin treatment after being convinced by my hair (b) (4) . The owner of the salon, Mark Heavener, told me that I would "love it." After an approximately three hour process with excessive fumes and burning, the procedure was done. I was not allowed to wash my hair for three days. Within one week of receiving the keratin treatment, my hair began abnormally shedding excessively. Large chunks of my hair began falling out at the root and breaking off. When I washed it, my hair had a completely different texture that I can only describe as "mushy" when wet. I

More

6. Relevant Tests/Laboratory Data, Including Dates

Blood work to be done per my doctors requests.

More

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

No personal or family history of hair loss. No history of nosebleeds until keratin treatment.

More

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 Coppola keratin treatment
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(if unknown, give duration)* from/to *(or best estimate)*
#1 11/03/2012 -- 11/03/2012
#2 --

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

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

JUN 18 2013

3. Manufacturer Name, City and State
Salon Heavener, Laguna Hills, CA

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)*

None.

More

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

1. Name and Address
(b) (6)

Phone #
E-mail elenawelsh@hotmail.com

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

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

FORM FDA 3500 (6/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

000001

'13 JN 20

5153388

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

B5. Describe event or problem continued

continued losing excessive amounts of hair on a daily basis from the root. Within two weeks of receiving the keratin treatment, a bald spot on the top of my head appeared about the size of a quarter. The area was completely bald. Over the course of the next several months, my hair continued to fall out in chunks. The bald spot increased in size to about the size of my palm. During this time, I also developed nose bleeds which now come every two weeks. After seeing doctors, I was diagnosed with alopecia areata and have to receive cortisone injections on my head to hopefully stop the hair loss. This is quite traumatizing for someone who has had thick, long hair her entire life. I have never experienced hair loss and have not had nosebleeds until I received this keratin treatment. I believe the product used by this salon is toxic and should not have been used. The salon did not inform me of side effects and did not make me wear a mask while the procedure was being done. I am so traumatized over my loss of hair and bald spots. Seven months post-keratin treatment, my once thick mane has thinned out significantly and I continue to lose massive amounts of hair by the root daily and there is no end in site. Either the ingredients in the product caused me to lose my hair or the procedure was clearly done improperly.

169515

U.S. Department of Health and Human Services

Consumer Report

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

1/1 Page ~~1 of 2~~ CFSAN

FDA USE ONLY
Triage unit sequence # 522205

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	42 Years (b) (6)	☑ Female ☐ Male	104 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
08/15/2013	08/26/2013

5. Describe Event, Problem or Product Use Error

Went to Salon Ziba in Manhattan (NYC) on Thursday, 8/15/13 for Brazilian Keratin Treatment (Brazilian Blowout). Margerita placed solution directly on my scalp as if shampooing in my hair and scalp. I don't think the solution should have been placed directly on my scalp. The solution was never rinsed from my hair/scalp and I was instructed by Margerita to not wash it until the next day. During the treatment, I told Margerita that my scalp was burning. The next day, my scalp, eyes, nose and throat were burning and I was having difficulty breathing. I washed it out once I woke up.

6. Relevant Tests/Laboratory Data, Including Dates

Went to doctor on Monday, 8/19/13 complaining of back pain near kidneys, nausea, burning scalp, eyes, nose, throat, and hair loss since Brazilian keratin treatment on 8/15/13. My doctor ran blood test.

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

Race:White Medical Conditions: n/a Allergies: nuts, pollen Important Information: n/a RX Meds: n/a OTC Meds: n/a

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: Brazilian keratin treatment
Strength:
Manufacturer: brazilian blowout

#2 Name:
Strength:
Manufacturer:

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

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 08/15/2013 –
#2

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

4. Diagnosis or Reason for Use (Indication)
#1 Salon treatment to smooth hair
#2

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name CTU

3. Manufacturer Name, City and State AUG 27 2013

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

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

'13 AUG 28

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

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

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

PLEASE TYPE OR USE BLACK INK

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

000001

[Close]

FACTS Interface

FACTS Complaint #130790 (CAERS #169965)			
Complaint Date	02/19/2013	**Complaint Source**	Consumer
Accomplishing District	NWJ-DO	**Complaint Status**	Archived
How Received	Email		

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 Consumer alleged she experienced an allergic reaction after using Suave Keratin Infusion Conditioner on 2/13. Within a day she developed hives all over her body. Reaction began on her scalp which was red, bumpy and itchy. It moved to the back of her neck, down her torso and to her legs. She saw a doctor on 2/14 and been on a tapered dose of Prednisone along with antihistamines. By 2/19 her condition has improved. Other product used for haircare is John Frieda shampoo. She's 60 yrs old, born 12/3/1952. She threw remaining product away and does not have any product codes. Product was purchased the week of Feb 4th, 2013 from CVS.	**Adverse Event Result**	None
	Adverse Event Date	2/14/2013
	Notify EIO/EMOPS?	Yes
	Notification Date	02/19/2013
	Attended Health Professional?	Yes
	Required Hospitalization?	No
	Emergency Room/ Outpatient Visit?	No
	Reported Complaint To?	Unknown
	Need Additional/ FDA Contact?	No
Remarks No product is remaining		

Complaint Symptoms		
Symptom Name	**Duration**	**Remarks**
Hives (urticaria, welts)	5 Day(s)	Hives all over body
Itching	5 Day(s)	scalp

Health Care Professional					
Health Care Type	**Provider Name**	**Address**	**Phone**	**Occupation**	**Stay Dates**
(b) (4)	(b) (4)	(b) (4)	(b) (4)		

Product and Labeling			
Brand Name	Suave		
Product Name	Keratin Infusion Conditioner		
FDA Product Code	53ED03	**Qty/Unit**	
UPC Code	not available	**Package**	Bottle
Exp/Use By Date	not available	**Lot/Serial**	not available
Product Used?	Yes	**Purchase Date**	02/2014
Date Used?	02/13/2013	**Amount Consumed/Used**	1 bottle
Amount Remained	none	**Date Discontinued**	02/13/2013
Country of Origin		**Imported Product?**	No
Retailer Name	CVS	**Label Remarks** Unilever	

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3004778869	Unilever United States. Inc. 800 Sylvan Ave Englewood Cliffs NJ 07632-3113	NWJ-DO	Corporate Headquarters

Initial Evaluation / Initial Disposition

Initial Evaluation	FDA Action Indicated	**Initial Disposition**	Referred to Other FDA District
Disposition Date	09/13/2013		

Remarks

NWE-DO contacted Unilever and spoke with Lauren Mulroy to identify the manuf. 201-227-5921. She said without the lot or UPC she can not determine the location of the plant. CC was referred to NWJ-DO as FYI.

Problem Keyword	Problem Keyword Details
Allergic Reaction	itching, redness, hives

Cosmetic

Cosmetic ID	(b) (6)		
DOB	(b) (6)	**Age**	60
Gender	Female	**Race**	Unknown
Application Place	Home	**Reason for Use**	Hair Preparations (Non-Coloring)
Application Site	Hair	**Other Products?**	Yes
Directions			
Yes			
Directions Followed?	Yes	**Product Duration**	Day(s)
Frequency of Use	Other	**Reaction Site**	Scalp
Product Use in Off-Label Manner?	No	**Off-Label Manner Desc**	
Warning Statement on Label?		**Warning Statements?**	
Preexisting Conditions?		**Treatment**	Physician
Current Status	Improved		
Medical Diagnosis		**Medical Treatment**	

Remarks

Used once

Adverse Events

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

[Close]

September 24, 2013

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 169965.

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

Sincerely yours,

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

Enclosure

170162

Consumer Report

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

1/1 Page ~~1 of 2~~ CTSN

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

FDA USE ONLY
Triage unit sequence # 524212

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
(b) (6)	51 Years	☑ Female ☐ Male	150 lb or ____ kg
In confidence	(b) (6)		

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)
09/13/2013	09/14/2013

5. Describe Event, Problem or Product Use Error

I had the Brazilian Blow Out treatment done on my hair yesterday. I had breathing problems and my eyes hurt that much that I was in tears. I didn't sleep last night because I have a terrible headache and my eyes are very irritated. I feel very sick.

6. Relevant Tests/Laboratory Data, including Dates

CTU

SEP 16 2013

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

Race:-- Medical Conditions: none Allergies: none Important Information: none RX Meds: none OTC Meds: vitamin D

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: brazilian blow out
Strength:
Manufacturer: brazilian blow out

#2 Name:
Strength:
Manufacturer:

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

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

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

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

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

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

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

Phone #	E-mail
(b) (6) 9	(b) (6)

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

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

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

September 23, 2013

Brazilian Blowout
6855 Tujunga Ave
North Hollywood, California 91605-6312

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 # 170162.

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

Sincerely yours,

Debra G. Street

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

Enclosure

170285

U.S. Department of Health and Human Services

Consumer Report

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Page 1 of 2

CTSN

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

FDA USE ONLY

Triage unit sequence # B24617

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b)(6) In confidence	45 Years (b) (6)	☑ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
07/23/2010	09/17/2013

5. Describe Event, Problem or Product Use Error

July, 2010 Female age 45 - Salon used Pravana smoothing treatment (Keratin Treatment). I was told not to wash my hair for 3 days. After my first hairwash my shower drain was filled with an alarming amount of hair and my scalp, neck and body were itching for months. My hair has continued to fall out (from the root), and is presently still shedding 3 years later. Initially a lot of the hair strands that fell out were thin and looked almost clear. I have lost about 1/2 the hair on my scalp and doctors say it could be from the keratin treatment (which was supposedly formaldahyde free) but they ...

6. Relevant Tests/Laboratory Data, Including Dates

Blood tests from 2010 to present checking for thyroid issues, hormone levels, and other deficiencies.

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

Race:-- Medical Conditions: Elevated cholesterol level Allergies: pollen, ragweed, cats Important Information: Healthy, active, never lost/shed hair before July of 2010 RX Meds: steroid foam was used OTC Meds: viviscal, daily multivitimins, biotin, iron supplements were all used

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)

4. Name, Strength, Manufacturer (from product label)

#1 Name: Pravana Smoothing System
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

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

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

#1
#2

5. Event Abated After Use Stopped or Dose Reduced?

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

4. Diagnosis or Reason for Use (Indication)

#1 Keratin treatment to smooth hair
#2

6. 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: GTN

2. Common Device Name: SEP 18 2013

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address

Name: cathy dipenta
Address:
City: State: -- ZIP:

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

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

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

'13SP 28

PLEASE TYPE OR USE BLACK INK

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

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PAGE 15/27 MED WATCH 18003320178 09/18/2013 15:34

524617

U.S. Department of Health and Human Services

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)
For VOLUNTARY reporting of adverse events and product problems

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

... can't know for sure. I have had many blood tests for possible causes and nothing comes up. THE HAIRLOSS STARTED AFTER THE KERATIN TREATMENT. I NEVER HAD IT BEFORE THE TREATMENT. SOMETHING HAPPENED TO MY HAIR WITH THE CHEMICALS THAT WERE USED. The salon said nobody else has complained...but would they tell me if they had? I have had some regrowth but that hair is very fine and also falls out. IT STARTED IMMEDIATELY AFTER THE KERATIN TREATMENT. I have used steroid creams, special shampoos, and am considering minoxidil. While the loss includes the front and crown I have all over thinning.

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

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

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

September 26, 2013

Pravana Naturceuticals .
23285 Ventura Blvd
Woodland Hills, California 91364

To Whom It May Concern:

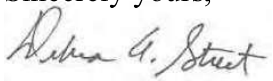
This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (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 # 170285.

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

Sincerely yours,



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

Enclosure

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Page ____ of ____

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

FDA USE ONLY

Triage unit sequence #	I1390487A
	170362

A. PATIENT INFORMATION

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

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/25/2013	09/23/2013

5. Describe Event, Problem or Product Use Error

See attached:

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Brazillian Blowout (Original) Hair
#2 Straightening

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

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

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

6. 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

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

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

PLEASE TYPE OR USE BLACK INK

This is a copy of your Report to the U.S. Consumer Product Safety Commission submitted on 9/23/2013

Incident Details

Document Number:	I1390487A
Report Number:	20130923-98F41-2147451605
Report Submitted Date:	9/23/2013
Who You Are:	Consumer
Incident Description:	I had a certified salon professional use the Brazilian Blowout (Original) hair straightening treatment on my hair. Immediately following this treatment, my hair began falling out. At first, I thought it was only shedding due to the harsh chemicals and it would be temporary. However, it continued. It has not stopped "shedding" since April and I have now lost almost half of my hair. Other people have noticed and began telling me, including my salon professional who has been cutting my hair for years. I have just ordered hair vitamins and plan to see my dermatologist as well. My hair has never fallen out before and I've always had very thick, curly, shiny and healthy hair. It is now damaged and I find clumps of hair in my shower and my brush and any time I touch my hair several strands just fall out. It is far beyond any norm in my 44 years. I'm extremely concerned about this product and I know the salon professional used all of the guidelines to administer it properly.
Incident Date:	3/25/2013
Incident Location:	Home/Apartment/Condominium - P.O. Box 5015, Santa Monica, California, 90409, United States

Victim Details

First Name:	(b) (6)
Last Name:	(b) (6)
Injury Information:	Incident, No Injury
Victim is of Hispanic/Latino origin?	No
Race:	White
Other Race/Ethnicity:	
My Relationship to Victim:	Self
Gender:	Female
Age when incident occurred:	44 Years
Address:	(b) (6)
E-mail:	(b) (6)
Phone Number:	(b) (6)

Product Details

Product Description:	Brazilian Blowout Acai Professional Soothing Solution (Original) Brazilian Blowout Acai Anti-Frizz Shampoo & Conditioner Brazilian Blowout Acai Daily Smoothing Serum Brazilian Blowout Acai Protective Thermal Straightening Balm

Product Category:	Personal Care
Product Type:	Grooming
Brand Name:	Brazilian Blowout
Manufacturer / Importer / Private Labeler Name:	BrazilianBlowout.com
Model Name or Number:	
Serial Number:	
Date Manufactured:	
Manufacturer Date Code:	
Manufacturer Address:	Not specified
Manufacturer Website URL:	
Manufacturer Phone Number:	
Retailer:	
Retailer State:	

Additional Details

Purchase Date:	
I still have the product in my possession.	Yes
The product was damaged before the incident.	No
The product was modified before the incident.	No
Have you contacted the manufacturer?	Yes
If not, do you plan to contact them?	N/A

Explanation: I contacted the mfg today for an Material Safety Data Sheet to bring to my dermatologist.

Your Contact Information

First Name: Marie

Last Name: Roviello

Address:	P.O. Box 5015, Santa Monica, California, 90409, United States
E-mail	(b) (6)
Phone Number:	(b) (6)

Consent	
May we include your Report, including any documents or photographs that you have attached to your Report, but without your name and contact information, in CPSC's Public Database?	Yes, you may include my Report with any attachments on SaferProducts.gov.
May we release your name and contact information to the product manufacturer / importer / private labeler identified in your Report?	Yes, you may release my name and contact information to the product manufacturer /importer / private labeler.
I certify that I have reviewed the Report and that the information provided in this Report is true and accurate to the best of my knowledge, information, and belief.	Yes

OMB Control Number (b) (6)

December 03, 2013

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 170362.

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

Sincerely yours,

Debra G. Street

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CFSAN

Form Approved: OMB No. 0910-029
Expiration Date: 6/30/201
(See PRA Statement on precedi general information pag

MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

115

172434

Section A – About the Problem

What kind of problem was it? *(Check all that apply)*

- [x] 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 *(Include date)*: _____
- [ ] Other serious/important medical incident *(Please describe below*

Date the problem occurred *(mm/dd/yyyy)*

May 2013 - August 2013

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

My hair dresser gave me a product to use in my hair to help with straightening. She said it was an all natural raw keratin protein. The distributor told her this and used it as a selling point. I used the product for a month. My hair began to present very oily, then it became stiff at the roots and started to fall out in hand fulls. I stopped using the product and thought the problem

Continuatio Page

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

CBC with diff/platelet, CMP, UA with culture, Lipid panel, Thyroid panel with TSH, Iron and TIBC, Vit B12 and folate, FSH and LH, Testosterone (free and total), Hemoglobin A1C, Estradiol, Rheumatoid Factor, Vit D, Hydroxy, C-reactive protein, Cardiac, Microalbumin, ANA with reflex, Sedimentation rate,and Progesterone. 8/7/13. The only abnormal was low Vit D and

Continuatio Page

For a problem with a product, including

- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

Go to Section B

For a problem with a medical device, including

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

Go to Section C (Skip Section B)

For more information, visit *http://www.fda.gov/MedWatch*

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

Section B – About the Products

Name of the product as it appears on the box, bottle, or package *(Include as many names as you see)*
Raw native keratin, Mane Tame, Keratin Spray

Name of the company that makes the product
Unknown - Distributed by Dan Gile Distribution - 601 N congress ave, suite 503, Delray Beach, FL 33445. 877-243-7980

Expiration date *(mm/dd/yyyy)*	Lot number	NDC number
NA	NA	NA

Strength *(for example, 250 mg per 500 mL or 1 g)*	Quantity *(for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)*	Frequency *(for example, twice daily or at bedtime)*	How was it taken or used *(for example, by mouth, by injection, or on the skin)*?
		1-3 times per week	sprayed onto and worked through hair

Date the person first started taking or using the product *(mm/dd/yyyy)*: 05/14/2013

Date the person stopped taking or using the product *(mm/dd/yyyy)*: 06/04/2013

Why was the person using the product *(such as, what condition was it supposed to treat?)*
Help moisturize and straighten hair.

Did the problem stop after the person reduced the dose or stopped taking or using the product? ☐ Yes ☒ No

Did the problem return if the person started taking or using the product again? ☐ Yes ☐ No ☒ Didn't restart

Do you still have the product in case we need to evaluate it? *(Do not send the product to FDA. We will contact you directly if we need it.)* ☒ Yes ☐ No

☐ **Go to Section D (Skip Section C)**

Section C – About the Medical Device

Name of medical device

Name of the company that makes the medical device

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

Was someone operating the medical device when the problem occurred?
☐ Yes
☐ No

If yes, who was using it?
☐ The person who had the problem
☐ A health professional *(such as a doctor, nurse, or aide)*
☐ Someone else *(Please explain who)*

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

Date the implant was put in *(mm/dd/yyyy)*	Date the implant was taken out *(If relevant) (mm/dd/yyyy)*

☐ **Go to Section D**

Section D – About the Person Who Had the Problem

Person's Initials	Sex	Age *(at time the problem occurred)* or Birth Date	Weight *(Specify lbs or kg)*	Race
(b)(6)	☒ Female ☐ Male	32	135lbs	white

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

Raynaud's disease, Possible RA but no official diagnosis due to only abnormality is increased RA factor, HSV1, HPV, Acid Reflux

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

Amoxicillin, Bactrim, peaches, cantaloupe, seasonal allergies

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

drinks approximately 2 beers a day.

List all current prescription medications and medical devices being used.

Valtrex 500mg PRN

Continuation Page

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

Multi Vit, Vit D, Zantac, Claritin,

Continuation Page

Go to Section E

Section E – About the Person Filling Out This Form

We will contact you only if we need additional information. Your name will not be given out to the public.

Last name	First name
(b) (6)	(b) (6)

Number/Street	City and State/Province
(b) (6)	(b)(6)

Country	ZIP or Postal code
United States	(b) (6)

Telephone number	Email address	Today's date *(mm/dd/yyyy)*
(b) (6)	(b) (6)	(b) (6)

Did you report this problem to the company that makes the product (the manufacturer)?

☐ Yes ☒ No

May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product? ☒ Yes ☐ No

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA. Mail or fax the form to:

Mail:	Fax:
MedWatch Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	1-800-332-0178 (toll-free)

Thank you for helping us protect the public health.

For more information, visit *http://www.fda.gov/MedWatch*

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

Continued Entries

CONTINUED ENTRY FOR: Tell us what happened and how it happened. *(Include as many details as possible)*

would stop once it was washed out but my hair did not return to normal. After it came to my attention that my hair was dramatically thinner, I went to my PCP who ran multiple lab tests and then referred me to a dermatologist. There was no medical reason for my ha loss. I contacted my hair dresser who then contacted the distributor and again they told her there is no possible reason why the produ would cause hair loss because it is all natural. The distributor stated they have never heard of such a reaction. I researched the produc more on my own and found it to contain Formalin which, I then learned to be a form of Formaldehyde. I lost half of my hair until the hair loss finally stopped on it's own. This started in May 2013 and finally stopped at the end of August 2013. Since, my hair has start to grow back. I was psychologically distraught through out this process. I cried every time I took a shower or ran my hands through my hair. I am concerned that this product is being falsely advertised and promoted. I would have never used it if it had not been advertised as a "raw native keratin." I have included pictures of the product.

Back to For

CONTINUED ENTRY FOR: List any relevant tests or laboratory data if you know them. *(Include dates)*

High RA factor which I already knew were abnormal, and have been followed by my doctor, due to testing from 2/24/12.

Back to For

CONTINUED ENTRY FOR: List all current prescription medications and medical devices being used.

Back to For

CONTINUED ENTRY FOR: List all over-the-counter medications and any vitamins, minerals, and herbal remedies being used.

Back to For

Food and Drug Administration
Center for Food Safety and Applied Nutrition
CFSAN Adverse Events Reporting System
(CAERS)

CAERS #

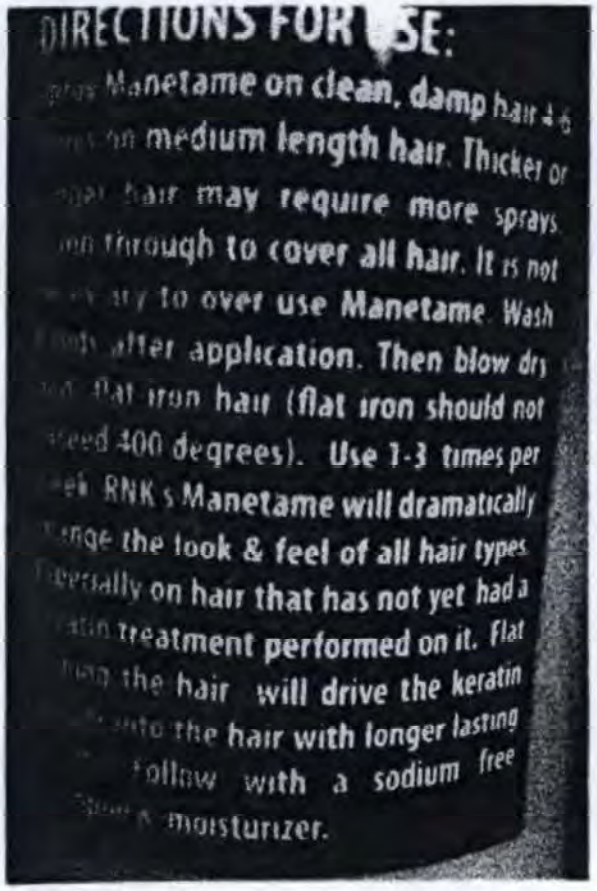
172434

2 - LABEL SAMPLE

000001

53307


RNK
TAME
10 FI OZ


DIRECTIONS FOR USE:
Manetame on clean, damp hair
on medium length hair. Thicker or
hair may require more sprays
through to cover all hair. It is not
to over use Manetame. Wash
after application. Then blow dry
flat iron hair (flat iron should not
400 degrees). Use 1-3 times per
RNK s Manetame will dramatically
the look & feel of all hair types
especially on hair that has not yet had a
treatment performed on it. Flat
the hair will drive the keratin
into the hair with longer lasting
follow with a sodium free
moisturizer.


NORTH CONGRESS AVE. SUITE 505


ed from NEW ZEALAND
tive Kerati is a keratin
in nature therefore
hair more effectively
kera in.
OF REACH OF CHILDREN
ACH FL 33445 • 877.245.7988

CFSAN 173153

U.S. Department of Health and Human Services

Internet Consumer Report

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

1/3

FDA USE ONLY
Triage unit sequence # 533971

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
(b) (6) in confidence	37 Years (b) (6)	☑ Female ☐ Male	155 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)*
10/28/2013	12/14/2013

5. Describe Event, Problem or Product Use Error

I have been a hairdresser for 17 yrs and salon owner for 11 yrs now. A rep for the company Brazilian Blow out who is a friend of a close friend of mine approached me at a mutual function. The rep asked me why I didn't provide their service in my salon and how much more $ I could be making etc. I hadn't heard much about this product/co. at this time for several yrs. now. I told her I was not going to subject myself or clientele to formaldehyde exposure. This conversation went on for approx 40 min. She assured me all the hype was not true and the product did not contain formaldehyde, it was made ...

6. Relevant Tests/Laboratory Data, Including Dates

Through thoroughly researching this topic and my ongoing health issues; I have found this to be more serious than I first thought. I have read from a victim with similar symptoms that I need to find a toxicologist for specific blood tests & a industrial hygienist for hair sample. Primary care DRs do ...

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

Race: White

Medical Conditions: 2 herniated discs in back & neck issues from car accident in 2005 and fibromyalgia
---
Allergies: None

Important Information: Do not smoke or drink

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: Brazilian blow acai solution
Strength: Original
Manufacturer: Brazilian blow out

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	One time	On hair
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 Oct 28th 2013 to present
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Straightening hair styling ease believed to be safe product
#2

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU
DEC 16 2013

3. Manufacturer Name, City and State

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

1. Name and Address

Name: Jana Johnston
Address:
City: State: -- ZIP:

Phone #	E-mail
	Jana-johnston@hotmail.com

2. Health Professional?	3. Occupation	4. Also Reported
☐ Yes ☐ No		☑ Manufa ☐ User ☐ D

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 contribute

533971

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

... up of amino acids and acai berry. She then said I would be a perfect candidate for the service due to my fine, highlighted, curly hair. She once again assured me by telling me consider it a conditioning treatment that will leave the most unruly damaged hair straight and shiny. I had told her about 4.5 yrs ago I had it done and it was a timesaver and my hair was nice. At this point she asked if I would be a hair model for the class to train licensed stylists how to perform this service a few days later. I went home looked up the MSDS and could not find any formaldehyde compound so I agreed. This was the worst mistake of my life! The day of the class I showed up at the Hilton in LaJolla CA. I was bent over a public bathroom sink to wash 1/2 my head for the before and after pics. for their website. I had reviewed the steps of the service on their website the night before to familiarize myself with the procedure. During the application my eyes, nose and throat were burning, the stylist who did the service told me to close my eyes. After the class left and they got their photo I was told time was running late and the Co. started packing up the merchandise they hadn't sold. I was expecting the next step whic was to rinse the chemical out of my hair. The stylist told me to rinse it myself when I got home but not to shampoo it. I questioned him on the safety of this and he said I could safely leave it in for "a few days and it would be fine." Hesitantly I said ok and asked to see a mirror. The rep and the stylist kept commenting on how great it looked. I saw that my hair looked very dull, dry, and the color had been stripped out. I told the rep. that this was supposed to do the opposite, she claimed it looked great. I left and went to my regular monad scheduled accupuncture apt. This is when I really started noticing a bad reaction. While driving to my apt I felt like mt neck and scalp were on fire. Apon getting to my destination I felt dizzy and nauseous. Within 4.5 hrs getting this treatment done I got home and rinsed and conditioned as directed. I had blisters on my scalp and back of neck. My hair felt like hay and was way thinner than normal. I didn't even dry my hair due to the pain on my scalp. The next day I had all of the same symptoms and started vomiting up to 3xs a day. This proceeded with chunks of hair broken off and flu like symptoms. I missed a week of work, too out of it to leave my bed. At this point I realized there was something linking the illness with the use of this product and it's shampoo conditioner and mask as directed. I started documenting my hair loss and varying health concerns via numerous pictures and daily journal entries. I did contact the rep 4 days post treatment to tell her I had blisters and my hair was chemically burned off. She asked to see the few pics. I had at the time and called back horrified! She finally told me this actually happened to her the 1st weeks of her employment with this co. And said he had used way to high of heat for my hair which caused this reaction and no cape to protect my skin. Fast forward to today 5 weeks later i haven't felt myself since I had this keratin treatment done! I'm scared with all the health issues arising including; nose bleeds, flu that never ends,burning and red rashes after showering,muscle pain, weight loss, headaches, insomnia,confusion,shaking,anxiety attacks

533971

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

... not deal with chemical poisoning, or even know the correct tests to order for formaldehyde. I am now trying to figure out how to afford the thousands of $ of tests my insurance won't cover.

533971

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

, , , b12

CFSAN

U.S. Department of Health and Human Services — Internet Health Professional Report — Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

FDA USE ONLY
Triage unit sequence # 533969

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	37 Years	☑ Female ☐ Male	155 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/28/2013	12/14/2013

5. Describe Event, Problem or Product Use Error
Scalp & nape of neck was blistered while a employee of the co.performed a Brazilian blow out on me as a model. My hair continually breaks, some around my hairline by the roots. Major health concerns since day of service nose, eyes, and sinus burning. But a majority 4 days following. Including dizziness, flu symptoms, sore throat, nose bleed, chest tightness, insomnia, nausea, cognitive issues, headaches, random metallic taste in mouth, burning bumps & redness on legs after shower, fatigue, muscle pain, hot & cold tingling hands, and anxiety. Many of these symptoms are daily,I haven't felt ...

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
No allergies non smoker non drinker, white. No issues prior.

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Brazilian Blow Out
Strength: Original
Manufacturer: Brazilian blow out

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 Once	Used after care	Topical
#2		

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

4. Diagnosis or Reason for Use *(Indication)*
#1 This was supposed to condition, smooth frizz, and seal color
#2

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Brazilian blow out

CTU
DEC 16 2013

2. Common Device Name
Original

3. Manufacturer Name, City and State
Brazilian blow out
Los Angeles CA US

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
I was using the Brazilian Blow Out aftercare shampoo, mask, serum, daily styling cream, and straightening balm. I ...

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

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

Phone #	E-mail
	(b) (6)

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

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

PLEASE TYPE OR USE BLACK INK

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

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5339699

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

... myself in over a month and a half! It's believed the flat iron was used at too high of heat along with the fact that I was sent home with the chemical in my hair to rinse myself.

March 12, 2014

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 # 173153.

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

Sincerely yours,

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

Enclosure

[Close]

FACTS Interface

FACTS Complaint #135401 (CAERS #173404)			
Complaint Date	12/24/2013	**Complaint Source**	Consumer
Accomplishing District	NYK-DO	**Complaint Status**	Archived
How Received	Telephone		

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

Complaint / Injury		
Complaint Description	**Adverse Event Result**	Life Threatening
42 year old female complainant with no known allergies and no medical conditions believes Peter Coppola Keratin Smoothing Treatment is cause for her symptoms. Complainant worked at a salon for 1 year and 2 months and was a very active person. From 12/09 to 8/11 complainant serviced clients with smoothing treatments on an average of twice per week. After about a year, complainant developed symptoms of coughing up brownish/yellowish flem, a continuous cough, raspy voice and chest pains. Complainant noted that other stylist were experiencing similar symptoms and determined that symptoms must be related to product in question due to the amount of excess fumes involved with the smoothing treatmemts. Complainant discontinued use of product in question in 08/11 however her symptoms persist. In 09/12 complainant was diagnosed with auto immunune disorder. She has persistent chest pains and requires steam to improve her breathing. She has also developed swelling in her legs and was recently approved for disability due to her ongoing conditions.	**Adverse Event Date**	08/2011
	Notify EIO/EMOPS?	Yes
	Notification Date	12/24/2013
	Attended Health Professional?	Unknown
	Required Hospitalization?	No
	Emergency Room/ Outpatient Visit?	No
	Reported Complaint To?	FDA
	Need Additional/ FDA Contact?	
Remarks		

Complaint Symptoms		
Symptom Name	**Duration**	**Remarks**
Local swelling	null null	Swollen legs
Chest Pain	null null	Continuous pain
Coughing	null null	Persistent cough
Excessive phlegm production	null null	Coughing up brownish/yellowish flem
Difficulty breathing	null null	Has labored breathing and needs steam to help relieve
NEC - Identify in Remarks	null null	Auto immune disorder, raspy voice

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

Product and Labeling			
Brand Name	Peter Coppola		
Product Name	Keratin Smoothing Treatment		
FDA Product Code	53ED03	**Qty/Unit**	

UPC Code	UNK	**Package**	Bottle
Exp/Use By Date	UNK	**Lot/Serial**	UNK
Product Used?	Yes	**Purchase Date**	UNK
Date Used?	12/09 - 08/11	**Amount Consumed/Used**	UNK
Amount Remained	N/A	**Date Discontinued**	08/2011
Country of Origin		**Imported Product?**	No
Retailer Name		**Label Remarks**	

Manufacturer/Distributor

There is no firm information listed for this consumer complaint report.

Initial Evaluation / Initial Disposition

Initial Evaluation	Insuffici. Info, unable to evaluate	**Initial Disposition**	Closed w/o further Investigation
Disposition Date	01/23/2014		

Remarks

12/2013***Customer Service, 855-426-7765, awaiting vendor response****Per customer service. Their product is a new line just lauched 6/13. It has been many times confused with old line. The old line is via Keratin Complex, HQ at 888-409-4445.*** 1/6/14 Called number provided for old line. Awaiting vendor response**** 1/13/14 Called again. Second request***Per Marino Salvano, 888-409-4445 X334, complaints are forwarded via the FDA CAERS System. The company will not release information via phone request.****Sent email to CFSAN for their assistance.**** 1/17/14 Sent second request for assistance via email. Awaiting reply/assistance.*** 1/23/14 To date, no response from CFSAN and company was uncooperative.

Problem Keyword	Problem Keyword Details
Reaction	Developed persistent cough, coughs up flem, chest pains, raspy voice, swollen legs

Cosmetic

Cosmetic ID #25183

DOB		**Age**	42
Gender	Female	**Race**	White
Application Place	Salon/SPA	**Reason for Use**	Hair Preparations (Non-Coloring)
Application Site	Hair	**Other Products?**	

Directions

Unknown

Directions Followed?	Yes	**Product Duration**	
Frequency of Use	Other	**Reaction Site**	Chest
Product Use in Off-Label Manner?	No	**Off-Label Manner Desc**	
Warning Statement on Label?		**Warning Statements?** Unknown	
Preexisting Conditions?	No	**Treatment**	Physician
Current Status	Worsening		
Medical Diagnosis Auto Immune Disorder		**Medical Treatment** On going	

Remarks

Product used an average of twice per week***Per complainant, she followed product directions as well as received training for application of product

Adverse Events

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

[Close]

KERATINCOMPLEX.
WWW.KERATINCOMPLEX.COM

173404-001
173463-001

March 24, 2014

CFSAN / CEARS Staff
(HFS-11), 5100 Paint Branch Parkway
College Park, MD 20740

Re: Keratin Complex CFS Notice #173404/173463

Dear CFSAN / CAERS Staff:

This letter responds to your request for a response to your inquiry letter of February 6, 2014, relating to the salon professional health concerns claimed to be related to use of our products.

Please be advised that Keratin Complex has an extensive and detailed training and certification program for salon professionals who use our products. This program must be fully deployed and the certification process completed before salon professionals may use our products. These programs are specifically designed to avoid any sensory or dermal irritation that may arise from the use of our products. We are confident, based on our experience and the level of depth of these programs, that when they are followed, the risk of the kind of exposure concerns expressed in the noted communication are extremely low if not non-existent.

As well, Keratin Complex maintains a strict monitoring program in support of these training and certification processes, such that if it comes to our attention through our distribution network that any salons or salon professionals using our products are not compliant with our training and certification programs, we remove product from those salons until compliance is achieved. And we work closely with our distribution and salon partners to ensure that only the highest standards of employee and consumer health and safety are maintained.
In addition, we have an extensive internal system for tracking complaints regarding our products, and which such complaints contain sufficient information for us to communicate directly with the location where the complaint has arisen, we interact directly with salons in those instances to ensure that health and exposure concerns are addressed and do not re-occur.

'14 MR 26

6400 CONGRESS AVENUE • BOCA RATON, FL • 33487 TF: 888.409.4445 P: 561.206.6050 F: 561.206.6051

KERATINCOMPLEX.
WWW.KERATINCOMPLEX.COM

Furthermore, as you are likely aware, there are a wide array of chemicals present in products in use on a regular basis within the salon environment which may cause the kind of concerns reflected in the noted communication.
In addition to these extensive programs and policies, we are aware that we must always exercise the highest levels of diligence in regards to consumer and salon professional health and safety. As a consequence, we are always looking at ways in which we can continuously improve our programs and procedures in this regard. Please know that we will continue to provide the highest level of attention to these matters. We appreciate your inquiry, and we would welcome the opportunity to provide you with more information as needed.

Sincerely,

Marina Salzano
Compliance and Regulatory Manager
Keratin Complex Smoothing Therapy

6400 CONGRESS AVENUE • BOCA RATON, FL • 33487 TF: 888.409.4445 P: 561.206.6050 F: 561.206.6051

February 06, 2014

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 173404.

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

Sincerely yours,

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

Enclosure

U.S. Department of Health and Human Services

Internet Consumer Report CTSAC

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

1/3

FDA USE ONLY
Triage unit sequence # 537447

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	36 Years (b) (6)	☑ Female ☐ Male	175 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
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
01/11/2014	01/23/2014

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

I had a brazilian blowout done by my stylist on January 11th, 2014. On Monday, January 13th I started feeling unwell and my asthma starting flaring(I have a history of asthma). By Wednesday, January 15th I could not go to work and have had to take FMLA until January 27th, 2014. I have been to the doctor several times and have been on steroids and antibiotics and am still having no improvement. I have just today realized the possible connection between my asthma attack and the brazilian blowout. I was never warned that it could effect my lungs. The stylist only said it might burn my eyes as she ...

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

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

Race:White

Medical Conditions: asthma, GERD, hiatal hernia, anxiety, depression, interstitial cystitis
---
Allergies: shellfish(iodine), erythromyocin, codeine

Important Information:

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

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

#1 Name: Brazilian Blowout
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

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

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1 01/11/2014 -
#2

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

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

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

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

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** CTU

3. **Manufacturer Name, City and State** JAN 24 2014

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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

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

Phone #	E-mail
	(b) (6)

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

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

PLEASE TYPE OR USE BLACK INK

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

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5374447

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

... straight ironed it. I had headaches for the first week as well. The headaches have gone away but now I am still short of breath and lethargic. I am going to contact my stylist to see what options I have to get this chemical out of my hair asap!

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

... omeprazole,zanaflex

OTC Meds: fish oil, vitamin D, iron, vitamin E, multivitamin

March 12, 2014

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 173431.

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

Sincerely yours,

Debra G. Street

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

Enclosure

U.S. Department of Health and Human Services

Internet Consumer Report FISAN

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

FDA USE ONLY
Triage unit sequence # 537637

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6)	30 Years	☑ Female ☐ Male	107 lb or ____ kg
In confidence	(b) (6)		

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
01/15/2014	01/25/2014

5. Describe Event, Problem or Product Use Error

I went to a salon for a keratin treatment. During my consult, the stylist told me it was natural, good for my hair, and that all her clients love it. I did a general search about Keratin treatments and it sounded like a good option. During the treatment my eyes starting to burn to the point where they started watering and I couldn't keep them open for the majority of the time I was there. The stylist said "oh that happens, just keep your eyes closed and it will get better." For the 20-30 minutes that the solution had to sit on my hair, the stylist just disappeared as if she didn't want to be ...

6. Relevant Tests/Laboratory Data, Including Dates

NA

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

Race:Black/African American

Medical Conditions: None

Allergies: None

Important Information: None

C. PRODUCT AVAILABILITY

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

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

D. SUSPECT PRODUCT(S)

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

#1 Name: Keratin treatment
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 01/15/2014 - 01/15/2014
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 For hair straightening.
#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
Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b) (6) ZIP: (b) (6)

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

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

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

PLEASE TYPE OR USE BLACK INK

FDA 3500 (1/09)

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

000001

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

... around the stuff. That night I went home and noticed some of the keratin mixture that had dried on the back of my neck so I just wiped it off with a wet tissue. The very next day a rash started to appear on the back of my neck. They were moist raised welts and were there for the next 3-4 days until it started to go down and dry out. I then did some more research and looked specifically for adverse reactions from keratin treatments. I was shocked at what I found, especially the fact about the treatments not being "natural" or chemical-free. I reached out to the Salon owner and she assured me that she only uses the best items at her salon and that she has had no other complaints. I met again with the stylist that worked on my hair and after looking at my neck she said it was just an allergic reaction and that the neck is usually a sensitive area. She also told me that they called the supplier and that there is nothing wrong with the keratin mixture and there are no chemicals. I asked if they had a list of the ingredients and she said no. So basically, the salon is just taking their word for it. I am not someone who has sensitive skin and I have no known allergies to anything. Something just didn't sit right with me about the whole situation. They couldn't explain why my eyes were burning and they didn't even bother to tell me about it beforehand. If I went to a doctor that gave me medicine and knew about side affects related to it and didn't bother to tell me, I wouldn't trust that doctor. At this point, I think the Salon is dismissing my experience there. Something is wrong with that mixture. Something that is "natural" shouldn't burn my eyes to the point where I can't even keep them open or cause my skin to welt. It has been about a week and a half since I had the treatment. The rash is now gone and so far no other anomalies have occurred.

[Close]

FACTS Interface

FACTS Complaint #135401 (CAERS #173463)			
Complaint Date	12/24/2013	**Complaint Source**	Consumer
Accomplishing District	NYK-DO	**Complaint Status**	Archived
How Received	Telephone		

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

Complaint / Injury		
Complaint Description	**Adverse Event Result**	Life Threatening
42 year old female complainant with no known allergies and no medical conditions believes Peter Coppola Keratin Smoothing Treatment is cause for her symptoms. Complainant worked at a salon for 1 year and 2 months and was a very active person. From 12/09 to 8/11 complainant serviced clients with smoothing treatments on an average of twice per week. After about a year, complainant developed symptoms of coughing up brownish/yellowish flem, a continuous cough, raspy voice and chest pains. Complainant noted that other stylist were experiencing similar symptoms and determined that symptoms must be related to product in question due to the amount of excess fumes involved with the smoothing treatmemts. Complainant discontinued use of product in question in 08/11 however her symptoms persist. In 09/12 complainant was diagnosed with auto immunune disorder. She has persistent chest pains and requires steam to improve her breathing. She has also developed swelling in her legs and was recently approved for disability due to her ongoing conditions.	**Adverse Event Date**	08/2011
	Notify EIO/EMOPS?	Yes
	Notification Date	12/24/2013
	Attended Health Professional?	Unknown
	Required Hospitalization?	No
	Emergency Room/ Outpatient Visit?	No
	Reported Complaint To?	FDA
	Need Additional/ FDA Contact?	
Remarks		

Complaint Symptoms		
Symptom Name	**Duration**	**Remarks**
Local swelling	null null	Swollen legs
Chest Pain	null null	Continuous pain
Coughing	null null	Persistent cough
Excessive phlegm production	null null	Coughing up brownish/yellowish flem
Difficulty breathing	null null	Has labored breathing and needs steam to help relieve
NEC - Identify in Remarks	null null	Auto immune disorder, raspy voice

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

Product and Labeling			
Brand Name	Peter Coppola		
Product Name	Keratin Smoothing Treatment		
FDA Product Code	53ED03	**Qty/Unit**	

UPC Code	UNK	**Package**	Bottle
Exp/Use By Date	UNK	**Lot/Serial**	UNK
Product Used?	Yes	**Purchase Date**	UNK
Date Used?	12/09 - 08/11	**Amount Consumed/Used**	UNK
Amount Remained	N/A	**Date Discontinued**	08/2011
Country of Origin		**Imported Product?**	No
Retailer Name		**Label Remarks**	

Manufacturer/Distributor

There is no firm information listed for this consumer complaint report.

Initial Evaluation / Initial Disposition

Initial Evaluation	Insuffici. Info, unable to evaluate	**Initial Disposition**	Closed w/o further Investigation
Disposition Date	01/23/2014		

Remarks

12/2013***Customer Service, 855-426-7765, awaiting vendor response****Per customer service. Their product is a new line just lauched 6/13. It has been many times confused with old line. The old line is via Keratin Complex, HQ at 888-409-4445.*** 1/6/14 Called number provided for old line. Awaiting vendor response**** 1/13/14 Called again. Second request***Per Marino Salvano, 888-409-4445 X334, complaints are forwarded via the FDA CAERS System. The company will not release information via phone request.****Sent email to CFSAN for their assistance.**** 1/17/14 Sent second request for assistance via email. Awaiting reply/assistance.*** 1/23/14 To date, no response from CFSAN and company was uncooperative.

Problem Keyword	Problem Keyword Details
Reaction	Developed persistent cough, coughs up flem, chest pains, raspy voice, swollen legs

Cosmetic

Cosmetic ID #(b) (6)

DOB		**Age**	42
Gender	Female	**Race**	White
Application Place	Salon/SPA	**Reason for Use**	Hair Preparations (Non-Coloring)
Application Site	Hair	**Other Products?**	
Directions Unknown			
Directions Followed?	Yes	**Product Duration**	
Frequency of Use	Other	**Reaction Site**	Chest
Product Use in Off-Label Manner?	No	**Off-Label Manner Desc**	
Warning Statement on Label?		**Warning Statements?** Unknown	
Preexisting Conditions?	No	**Treatment**	Physician
Current Status	Worsening		
Medical Diagnosis Auto Immune Disorder		**Medical Treatment** On going	

Remarks

Product used an average of twice per week***Per complainant, she followed product directions as well as received training for application of product

Adverse Events

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

[Close]

KERATINCOMPLEX.
WWW.KERATINCOMPLEX.COM

173404-001
173463-001

March 24, 2014

CFSAN / CEARS Staff
(HFS-11), 5100 Paint Branch Parkway
College Park, MD 20740

Re: Keratin Complex CFS Notice #173404/173463

Dear CFSAN / CAERS Staff:

This letter responds to your request for a response to your inquiry letter of February 6, 2014, relating to the salon professional health concerns claimed to be related to use of our products.

Please be advised that Keratin Complex has an extensive and detailed training and certification program for salon professionals who use our products. This program must be fully deployed and the certification process completed before salon professionals may use our products. These programs are specifically designed to avoid any sensory or dermal irritation that may arise from the use of our products. We are confident, based on our experience and the level of depth of these programs, that when they are followed, the risk of the kind of exposure concerns expressed in the noted communication are extremely low if not non-existent.

As well, Keratin Complex maintains a strict monitoring program in support of these training and certification processes, such that if it comes to our attention through our distribution network that any salons or salon professionals using our products are not compliant with our training and certification programs, we remove product from those salons until compliance is achieved. And we work closely with our distribution and salon partners to ensure that only the highest standards of employee and consumer health and safety are maintained.
In addition, we have an extensive internal system for tracking complaints regarding our products, and which such complaints contain sufficient information for us to communicate directly with the location where the complaint has arisen, we interact directly with salons in those instances to ensure that health and exposure concerns are addressed and do not re-occur.

'14 MR 26

6400 CONGRESS AVENUE • BOCA RATON, FL • 33487 TF: 888.409.4445 P: 561.206.6050 F: 561.206.6051

Furthermore, as you are likely aware, there are a wide array of chemicals present in products in use on a regular basis within the salon environment which may cause the kind of concerns reflected in the noted communication.
In addition to these extensive programs and policies, we are aware that we must always exercise the highest levels of diligence in regards to consumer and salon professional health and safety. As a consequence, we are always looking at ways in which we can continuously improve our programs and procedures in this regard. Please know that we will continue to provide the highest level of attention to these matters. We appreciate your inquiry, and we would welcome the opportunity to provide you with more information as needed.

Sincerely,

Marina Salzano
Compliance and Regulatory Manager
Keratin Complex Smoothing Therapy

6400 CONGRESS AVENUE • BOCA RATON, FL • 33487 TF: 888.409.4445 P: 561.206.6050 F: 561.206.6051

February 06, 2014

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

To Whom It May Concern:

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

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

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 173463.

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

Sincerely yours,

Debra G. Street

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

Enclosure

U.S. Department of Health and Human Services

Internet Consumer Report 575A7

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

FDA USE ONLY
Triage unit sequence # 544529

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event or Date of Birth: 36 Years (b) (6)	3. Sex ☑ Female ☐ Male	4. Weight 255 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
02/22/2014	03/24/2014

5. Describe Event, Problem or Product Use Error
Eyes burning, nose running and temporary hearing loss

6. Relevant Tests/Laboratory Data, Including Dates

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

Medical Conditions: premature atrial contractions

Allergies: bananas, avocado, melon, shellfish

Important Information:

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: brazilian blowout
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

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

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

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

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

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

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

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name
CTU

3. Manufacturer Name, City and State
MAR 25 2014

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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

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

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

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

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

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

000001

[Close]

FACTS Interface

FACTS Complaint #134917 (CAERS #175122)			
Complaint Date	11/08/2013	**Complaint Source**	Consumer
Accomplishing District	NWE-DO	**Complaint Status**	Archived
How Received	Telephone		

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

Complaint / Injury		
Complaint Description	**Adverse Event Result**	Life Threatening
Consumer states that she is a professional hairdresser and was hospitalized twice approximately one week after giving a keratin smoothing treatment to a client. Consumer went to the emergency room on 10/21/2013 complaining of difficulty breathing, and a productive cough with blood in the sputum. Consumer was treated with a cough suppressant and antibiotics and then released. Consumer returned to the emergency room the next day complaining of worsening symptoms. At that time she was admitted to the hospital. Consumer was hospitalized from 10/22/2013 until 10/26/2013. Consumer states that while hospitalized a lung biopsy was performed which indicated blood, fluid and unidentified white matter. Additionally she states that her liver function tests came back elevated. CT scan and xrays were normal. She is scheduled for a pulmonary function test next month	**Adverse Event Date**	10/21/2013
	Notify EIO/EMOPS?	Yes
	Notification Date	11/08/2013
	Attended Health Professional?	Yes
	Required Hospitalization?	Yes
	Emergency Room/ Outpatient Visit?	Yes
	Reported Complaint To?	Other
	Need Additional/ FDA Contact?	Unknown

Remarks

Consumer states that she continues to experience respiratory difficulty and is scheduled for a pulmonary function test next month. Consumer has a history of asthma for 25 years and currently utilizes a rescue inhaler. Also has a history of gastric bypass surgery ten years prior. In addition to the FDA, the consumer has contacted the retail establishment, the corporate headquarters of the retail establishment, OSHA, Clinton County Health Department and Albany County Health Department.

Complaint Symptoms		
Symptom Name	**Duration**	**Remarks**
Coughing	null null	Blood in Sputum

Health Care Professional					
Health Care Type	**Provider Name**	**Address**	**Phone**	**Occupation**	**Stay Dates**
Health Care Professional	(b) (4)	(b) (4)	(b) (4)		
Hospital	(b) (4)	(b) (4)	(b) (4)		10/22/2013 - 10/26/2013
Emergency Room	(b) (4)	(b) (4)	(b) (4)		10/21/2013

Product and Labeling	
Brand Name	Ion
Product Name	Keratin Smoothing Treatment

FDA Product Code	53ED03	**Qty/Unit**	12 Fluid ounces
UPC Code		**Package**	Bottle
Exp/Use By Date		**Lot/Serial**	
Product Used?	Yes	**Purchase Date**	07/01/2013
Date Used?	10/15/2013	**Amount Consumed/Used**	8 fl. oz.
Amount Remained	4 fl. oz.	**Date Discontinued**	10/15/2013
Country of Origin	United States	**Imported Product?**	No
Retailer Name	Sally Beauty Supply	**Label Remarks** Consumer states that there were no Lot numbers, UPC codes or expiration dates on product	

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3003714912	Sally Beauty Supply LLC 3001 Colorado Blvd Denton TX 76210-6802	DAL-DO	Distributor
1280090	Zoto's International, Inc. 100 Tokeneke Rd Darien CT 06820-4825	NWE-DO	Corporate Headquarters

Initial Evaluation / Initial Disposition

Initial Evaluation	FDA Action Indicated	**Initial Disposition**	Surveillance Info for Next EI
Disposition Date	03/31/2014		

Remarks
DAL-DO CCC determined mfr is Zoto's Darien, CT. NWE-DO called Zoto's Corporate office in Darien 203-655-8911 and left message for the manager in charge of the customer & salon section. Return phone call was never received. CC closed as surveillance info.

Problem Keyword	Problem Keyword Details
Reaction	respiratory distress

Cosmetic

Cosmetic ID #25167

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

Remarks
Reaction occured in the hair dresser applying the product to a client. The hair dresser complains of respiratory difficulty and a productive bloody cough requiring hospitalization.

Adverse Events

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

[Close]

April 04, 2014

Zoto'S International, Inc.
100 Tokeneke Rd
Darien, Connecticut 06820-4825

To Whom It May Concern:

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

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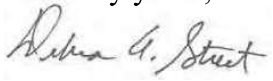
To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 175122.

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

Sincerely yours,



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

Enclosure