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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	20-Sep-2017	CTU Received Date	20-Sep-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

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
Did any of the following happen? (Check all that apply)	☑ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☑ Life-threatening ☐ Death ☑ Other serious/important medical incident
Other serious/important medical incident	Acute Myeloid Leukemia
Date the problem occurred	10-Feb-2017

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

In 2012, the FDA warned the makers of Keratin hair straighteners to remove formaldehyde from their products. The makers of Keratin Complex by Coppola removed formaldehyde, and replaced it with other toxic ingredients that when heated with the flat iron, which is required during this treatment, emits formaldehyde. I was diagnosed with Acute Myeloid Leukemia and I am convinced that it was from continuous use of this product during a 6-7 time period.

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

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle,	Keratin Complex by Coppola

	or package (Include as many names as you see)		
	Name of the company that makes (or compounds) the product	Coppola Beauty LLC	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		
	Is the Product Over-the-Counter?	Yes	
	Expiration date		
	Lot number		
	NDC number		
	Strength		If Other
	Quantity		If Other
	Frequency		If Other
	How was it taken or used		If Other
	Date the person first started taking or using the product		
	Date the person stopped taking or using the product		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No	
	Did the problem return if the person started taking or using the product again?	Doesn't Apply	
	Do you still have the product in case we need to evaluate it?	No	

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

Hair straightening

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)

	Model #	
	Catalog #	
	Serial #	
	Lot #	

Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6
Sex	
Age (specify unit of time for age)	52 Year(s)
Date of Birth	
Weight	63 kg(s)
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)

Product caused Acute Myeloid Leukemia and needs to be taken off the market.

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

N/A

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

No health products until diagnosed with Acute Myeloid Leukema.

List all current prescription medications and medical devices being used.

Acyclovir, Tacromilus, Magnesium Supplements, Entocourt

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

	N/A

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

	Product Name		
	Strength	If Other	
	Therapy Start Date		
	Therapy End Date		

Section E - About the Person Filling Out This Form

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

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	25-Feb-2018	CTU Received Date	25-Feb-2018
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

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
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date the problem occurred	24-Feb-2018

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

I went to have a brazilian blowout thinking only in having a smooth frizz free hair. However, the side effects of this product are horrible from headache back pain burning nose and throat. Worst experience in my life.

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

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout

	Name of the company that makes (or compounds) the product			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
	Is the Product Over-the-Counter?			
	Expiration date			
	Lot number			
	NDC number			
	Strength		If Other	
	Quantity		If Other	
	Frequency		If Other	
	How was it taken or used	Topical	If Other	
	Date the person first started taking or using the product			
	Date the person stopped taking or using the product			
	Did the problem stop after the person reduced the dose or stopped taking or using the product?			
	Did the problem return if the person started taking or using the product again?			
	Do you still have the product in case we need to evaluate it?	No		

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

Section C - About the Medical Device

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

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

	Model #	
	Catalog #	
	Serial #	
	Lot #	
	Unique Identifier (UDI) #	
	Expiry Date	

	Was someone operating the medical device when the problem occurred?	

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

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

Section D - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Sex	Female
	Age (specify unit of time for age)	23 Year(s)
	Date of Birth	
	Weight	56.25 kg(s)
	Ethnicity (Choose only one)	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)

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.

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

	Product Name		
	Strength	If Other	
	Therapy Start Date		
	Therapy End Date		

Section E - About the Person Filling Out This Form

	Last name	(b) (6)
	First name	(b) (6)
	Number/Street	
	City	
	State/Province	
	Country	USA
	ZIP or Postal code	
	Telephone number	
	Email address	
	Today's date	25-Feb-2018
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
	If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☑

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	High		
FDA Received Date	15-May-2018	CTU Received Date	15-May-2018
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)

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	Unspecified
	Age	69 Year(s)
	Date of Birth	
	Sex	Female
	Weight	49.5 kg(s)
	Ethnicity (Check single best answer)	Not Hispanic/Latino
	Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

	Check all that apply	☑ Adverse Event ☐ Product Use Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
	Serious	No
	Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☐ Life Threatening ☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events) ☐ Disability/Permanent Damage ☐ Congenital Anomaly/Birth Defect ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
	Date of Death	

Date of Event	01-May-2018
Date of this Report	15-May-2018

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Almost all of my hair has fallen out after using this product for six months.

Relevant Tests/Laboratory Data, Including Dates

Other Relevant History, Including Preexisting Medical Conditions

No pre-existing medical conditions, no other hair-care products

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	Yes
Returned to Manufacturer on	

D. PRODUCT(S) 1 of 1

Suspect	Yes		
Primary?	Yes		
Product Type	Drug/Biologic		
Product Name	Suave keratin infusion heat defense leave-in conditioner		
Strength		If Other	
Manufacturer/Compounder	L Oreal		
NDC# or Unique ID	79400 19391 9 no ND		
Is the Product Compounded?	Yes		
Is the Product Over-the-Counter?	Yes		
Event Abated After Use Stopped or Dose Reduced?	No		
Event Reappeared after Reintroduction ?	Doesn't Apply		

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency	Other	If Other	weekly
Route	Topical	If Other	
Dosage Form			
Therapy Start Date	01-Nov-2017		
Therapy End Date	01-May-2018		
Therapy Duration		If Other	

	Therapy Ongoing ?	
	Lot Number	none?
	Expiration Date	

Diagnosis or Reason for Use (indication) 1 of 1

	hair detangler

E. SUSPECT MEDICAL DEVICE

	Brand Name	
	Common Device Name	
	Procode	
	Manufacturer Name	
	City	
	State	
	Model #	
	Lot #	
	Catalog #	
	Expiration Date	
	Serial #	
	Unique Identifier (UDI) #	
	Operator of Device	☐ Health Professional ☐ Lay User/Patient ☐ Other
	Other	
	If Implanted, Give Date	
	If Explanted, Give Date	
	Is this a single-use device that was reprocessed and reused on a patient?	
	If Yes for the above field, Enter Name and Address of Reprocessor	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

	Primary?	Yes
	Reporter is Patient?	
	Title	
	Last Name	(b) (6)

	Middle Name		
	First Name	(b) (6)	
	Address	(b) (6)	
	City	(b) (6)	
	State/Province/Region	(b) (6)	
	Country	USA	If Other
	ZIP/Postal Code	(b) (6)	
	Phone	(b) (6)	
	Email	(b) (6)	
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Health Professional?	Yes	
	Occupation	Other Health Professional	If Other
	Also Reported to	☑ Manufacturer/Compounder ☑ User Facility ☑ Distributor/Importer	
	If you do NOT want your identity disclosed to the manufacturer	No	

CTU No.: FDA-CDER-CTU-2019-125387 | Department: CFSAN | RCT No.: RCT-639058 | CTU Triage Date: 28-10-2019 | Total Page s: 4

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-20180719747

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: [X] Year(s) [ ] Month(s) [ ] Week(s) [ ] Day(s): 68
or Date of Birth (e.g., 08 Feb 1925): 09-Sep-1959

3. Sex: [X] 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. [X] 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
[X] 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): 25-Oct-2019

5. Describe Event or Problem
This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.
The patient's weight, height and medical history were unknown.
Continued

6. Relevant Tests/Laboratory Data, Including Dates
On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown.
Continued

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#
	unknown
#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 26-Feb-2017 -
#2

5. Diagnosis for Use (Indication)
#1 UNKNOWN INDICATION
#2

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

10. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] 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
[X] Consumer
[ ] Health Professional
[ ] User Facility
[ ] Company Representative
[ ] Distributor
[ ] Other

Compounding Outsourcing Facility 503B? [ ] Yes

4. Date Received by Manufacturer (dd-mmm-yyyy): 27-Sep-2019

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

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
[ ] 5-day [X] 30-day
[ ] 7-day [ ] Periodic
[ ] 10-day [ ] Initial
[ ] 15-day [X] Follow-up # 5

Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC [ ] Yes

8. Manufacturer Report Number: 20180719747

9. Adverse Event Term(s)
1) CHEMICAL 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: (b) (6)
Phone #: Email: (b) (6)

2. Health Professional? [ ] Yes [X] 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...)

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386)(topical, dose and frequency unspecified) for unknown indication. Concomitant medications were not reported.
On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.
Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.
The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.
This report was associated with the product complaint and product complaint number was 30001451719.
This report was serious (medically significant).

Follow up information was received on 15-JUL-2018.
This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018.
This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Additional information was received on 30-AUG-2018.
This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information.
This case is a duplicate of 20181013176.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the

report.

Follow up information was received on 13-JAN-2019.
This report contains no new regulatory relevant information. No changes were made to the report.

Additional medically important information was received on 13-JAN-2019.
The patient stated that, the product made people sick.

Additional medically important information was received from patient on 01-JUN-2019.
On an unspecified date, patient developed formaldehyde poisoning and formaldehyde cancer (chemical poisoning) due to which she was getting sicker and sicker. Patient mentioned that formaldehyde got into her gum skin, eyes, nose, mouth, ears and bones. It was not going away and was affecting her health. The event of chemical poisoning and cancer did not resolve.

Additional medically important information was received from patient on 15-AUG-2019.
It was determined that Manufacturer Report Number 20190820522 was a duplicate of this case. All relevant information regarding this case will be submitted under Manufacturer Report Number 20180719747.
The following information was updated and incorporated into the case: The patient demographics were updated. It was reported that 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 patient had not recovered from hair loss and formaldehyde pockets in gums and the outcome of product label issue was unknown.

Additional information was received from patient on 15-JUL-2019. The following information was updated and incorporated into the case:
The reporter details were updated.

Additional information received from consumer on 27-SEP-2019. Upon review the following correction were done: On an unspecified date, the patient experienced redness on skin, blurriness and watering of the eyes, sores in mouth, infection of ears, nose, throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, snapping and rotting out of product from whole body (application site reaction), damaged skin and bones with swelling pain.
The patient had not recovered from redness on skin, blurriness and watering of the eyes, sores in mouth, infection of ears, nose throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, damaged skin and bones with swelling pain and the outcome of snapping and rotting out of product from whole body (application site reaction) was unknown.
The DC/RC was updated from unknown to not applicable for (chemical poisoning, formaldehyde pockets in gums, hair, bumps on body and cracks in head and product snapping and rotting out of whole body) . The DC/RC captured as unknown for mouth sores. The event of product quality complaint removed from case.
This case is duplicate of 20190939051, 20190623129, 20180125792, 20180902554, 20181202118, 20181217921, 20181113853, 20190609048, 20190821504, 20180133420, 20181117366, 20181216775, 20190822079, 20181013667, 20190626249, 20190701083 and 20180102688.

Company Remarks :

...

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

Lab Result :

Test name	Test date	Test result	Normal value	Classification
BIOPSY (Biopsy)		unknown		

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

Seq No. : 1
C.1 Suspect Product : OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ
C.9 Dechallenge : 2) N/A
: 3) UNK
: 4) UNK
: 5) UNK
: 6) UNK
C.10 Rechallenge : 2) N/A
: 3) UNK
: 4) UNK
: 5) UNK

:6) UNK

E. INITIAL REPORTER (Cont...)

State: Rhode Island
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) CHEMICAL POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
2) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))
3) HAIR LOSS (Application site alopecia (10059046), Application site alopecia (10059046))
4) MOUTH SORES (Sores mouth (10049318), Stomatitis (10042128))
5) BUMPS ALL OVER BODY (Application site papules (10049043), Application site papules (10049043))
6) CRACKS IN HEAD AND PRODUCT SNAPPING AND ROTTING OUT OF WHOLE BODY (Application site reaction (10003055), Application site reaction (10003055))

CTU No.: FDA-CDER-CTU-2018-70116 | Department: CFSAN | RCT No.: RCT-180449 | CTU Triage Date: 30-07-2018 | Total Pages : 3

JNJ Consumer US Cosmetic

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

MEDWATCH

3500A Facsimile

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

FDA Facsimile Approval: 01/30/2007

Mfr report #: US-JNJFOC-20180719747

UF/Importer report #:

FDA use only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	or Unknown Date of Birth: ??/??/????	☐ Female ☐ Male UNK	UNK lbs or UNK kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

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

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)*
??/??/????	07/27/2018

5. Describe Event or Problem

This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.

The patient's weight, height and medical history were unknown.

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified) for unknown indication. Concomitant medications

(Cont.)

6. Relevant Tests/Laboratory Data, Including Dates

No Relevant Test/Laboratory Data Reported.

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

No Relevant History Reported

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

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (OGX EVER STRAIGHTENING) Shampoo

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 Topical	#1 ??/??/????-??/??/????
#2	#2

4. Diagnosis for Use *(Indication)*

#1 PRODUCT USED FOR UNKNOWN INDICATION

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply UNK

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 unknown	#1 ??/??/????
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply UNK

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

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

No Concomitant Products Reported

D. 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

10. Device Available for Evaluation? *(Do not send to FDA)*

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

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of Event)*

E. INITIAL REPORTER

1. Name & Address

(b) (6)
UNITED STATES

Phone #

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

CTU No.: FDA-CDER-CTU-2018-70116 | Department: CFSAN | RCT No.: RCT-180449 | CTU Triage Date: 30-07-2018 | Total Pages : 3

JNJ Consumer US Cosmetic

MEDWATCH

3500A Facsimile *(Continued)*

FDA USE ONLY
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service ● Food and Drug Administration
FDA Use Only

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

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

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman
NJ
UNITED STATES

2. Phone Number: 1 -6094559402
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/15/2018
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(K)# ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ 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. Adverse Event Term(s): 1) CHEMICAL POISONING (Cont.)
9. Manufacturer Report Number: US-JNJFOC-20180719747

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ *No (Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and/or 11. ☐ Corrected Data

CTU No.: FDA-CDER-CTU-2018-70116 | Department: CFSAN | RCT No.: RCT-180449 | CTU Triage Date: 30-07-2018 | Total Pages : 3

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Skillman

Continuation Sheet for FDA-3500A Form

Mfr. report#: US-JNJFOC-20180719747
Date of this report: 07/27/2018

B5. Describe Event or Problem (Cont...)

were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.

Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant).

Senders Comments/Medical Assessment: .

G8. Adverse Event Term (Cont...)

2)PRODUCT FORMULATION ISSUE

CTU No.: FDA-CDER-CTU-2018-89122 | Department: CFSAN | RCT No.: RCT-200316 | CTU Triage Date: 27-09-2018 | Total Pages: 4

JNJ Consumer US Cosmetic

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

MEDWATCH
3500A Facsimile

CFSAN

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

FDA Facsimile Approval: 01/30/2007

MW report # US-JNJFOC-20180719747
LIR/sponsor report #
FDA use only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	or 68 Years	[X] Female [ ] Male	UNK lbs or UNK kgs
In confidence	Date of Birth: ??/??/????		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [X] Product Problem (e.g., defects/malfunctions)

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
- [X] 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)
??/??/????	09/20/2018

5. Describe Event or Problem

This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.

The patient's weight, height and medical history were unknown.

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified) for unknown indication. Concomitant medications

(Cont.)

6. Relevant Tests/Laboratory Data, Including Dates

No Relevant Test/Laboratory Data Reported.

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

No Relevant History Reported

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

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (OGX EVER STRAIGHTENING) Shampoo
#2

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) (or best estimate)
#1 Topical	#1 02/26/2017-??/??/????
#2	#2

4. Diagnosis for Use (Indication)
#1 PRODUCT USED FOR UNKNOWN INDICATION
#2

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

6. Lot #	7. Exp. Date
#1 unknown	#1 ??/??/????
#2	#2

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

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
No Concomitant Products Reported

D. 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

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of Event)

E. INITIAL REPORTER

1. Name & Address	Phone #
(b) (6) UNITED STATES	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
[ ] Yes [X] No	Unknown	[ ] Yes [ ] No [X] Unk

CTU No.: FDA-CDER-CTU-2018-89122 | Department: CFSAN | RCT No.: RCT-200316 | CTU Triage Date: 27-09-2018 | Total Pages : 4

JNJ Consumer US Cosmetic

MEDWATCH

3500A Facsimile *(Continued)*

FDA USE ONLY
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration
FDA Use Only

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___
11. Report Sent to FDA? ☐ Yes (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: (Specify)
13. Report Sent to Manufacturer? ☐ Yes (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman
NJ
UNITED STATES

2. Phone Number
1
-6094559402

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

4. Date Received by Manufacturer (mm/dd/yyyy)
08/30/2018

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(K)# ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ 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 #
1

8. Adverse Event Term(s)
1) CHEMICAL POISONING
(Cont.)

9. Manufacturer Report Number
US-JNJFOC-20180719747

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)* Method ___ - ___ - ___ - ___ Results ___ - ___ - ___ - ___ Conclusions ___ - ___ - ___ - ___
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360I(f), list correction/removal reporting number:
10 ☐ Additional Manufacturer Narrative and/or 11. ☐ Corrected Data

CTU No.: FDA-CDER-CTU-2018-89122 | Department: CFSAN | RCT No.: RCT-200316 | CTU Triage Date: 27-09-2018 | Total Pages : 4

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Skillman

B5. Describe Event or Problem (Cont..)

were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.

Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant).Follow up information was received on 15-JUL-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Additional information was received on 30-AUG-2018.

This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171106730, 20171120957, 20180324707,

CTU No.: FDA-CDER-CTU-2018-89122 | Department: CFSAN | RCT No.: RCT-200316 | CTU Triage Date: 27-09-2018 | Total Pages : 4

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199 Grandview Road
Skillman

Mfr. report#: US-JNJFOC-20180719747
Date of this report: 09/20/2018

Continuation Sheet for FDA-3500A Form

20180828488, 20180901076, 20180903071 and 20180724202.

Senders Comments/Medical Assessment:

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

Lab Result:

Test Name	Test Date	Test Result	Normal High	Normal Low
BIOPSY	??/??/????	unknown		

G8. Adverse Event Term (Cont...)

2) PRODUCT FORMULATION ISSUE

CTU No.: FDA-CDER-CTU-2019-10893 | Department: CFSAN | RCT No.: RCT-250117 | CTU Triage Date: 30-01-2019 | Total Pages: 4

CFSAN

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

MEDWATCH

3500A Facsimile

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

FDA Facsimile Approval: 01/30/2001

Mfr report #: US-JNJFOC-20180719747

IF/Importer report #:

FDA use only

A. PATIENT INFORMATION

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

2. Age at Time of Event: or 68 Years
Date of Birth: ??/??/????

3. Sex: [X] Female [ ] Male

4. Weight: ____ lbs or ____ kgs
UNK

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [X] Product Problem (e.g., defects/malfunctions)

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
- [X] 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): 01/25/2019

5. Describe Event or Problem

This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.

The patient's weight, height and medical history were unknown.

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified) for unknown indication. Concomitant medications

(Cont.)

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
No Relevant History Reported

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

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)
#1 OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (OGX EVER STRAIGHTENING) Shampoo
#2

2. Dose, Frequency & Route Used
#1 Topical
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 02/25/2017-??/??/????
#2

4. Diagnosis for Use (Indication)
#1 PRODUCT USED FOR UNKNOWN INDICATION
#2

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

6. Lot #
#1 unknown
#2

7. Exp. Date
#1 ??/??/????
#2

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

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
No Concomitant Products Reported

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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

Catalog # | Expiration Date (mm/dd/yyyy)

Serial # | Other #

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

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

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

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

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of Event)

E. INITIAL REPORTER

1. Name & Address
(b) (6)
UNITED STATES

Phone #

2. Health Professional? [ ] Yes [X] No

3. Occupation: Unknown

4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [X] Unk

CTU No.: FDA-CDER-CTU-2019-10893 | Department: CFSAN | RCT No.: RCT-250117 | CTU Triage Date: 30-01-2019 | Total Pages : 4

JNJ Consumer US Cosmetic

MEDWATCH

3500A Facsimile *(Continued)*

FDA USE ONLY
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration
FDA Use Only

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman
UNITED STATES

2. Phone Number 1 -60945594 02
3. Report Source *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other: ____
4. Date Received by Manufacturer (mm/dd/yyyy) 01/13/2019
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(K)# ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ 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 # 2
8. Adverse Event Term(s) 1) CHEMICAL POISONING (Cont.)
9. Manufacturer Report Number US-JNJFOC-20180719747

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date (mm/yyyy)
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)* Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number:
10 ☐ Additional Manufacturer Narrative and/or 11. ☐ Corrected Data

CTU No.: FDA-CDER-CTU-2019-10893 | Department: CFSAN | RCT No.: RCT-250117 | CTU Triage Date: 30-01-2019 | Total Pages : 4

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman

B5. Describe Event or Problem (Cont..)

were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.

Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant).Follow up information was received on 15-JUL-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Additional information was received on 30-AUG-2018.

This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was

CTU No.: FDA-CDER-CTU-2019-10893 | Department: CFSAN | RCT No.: RCT-250117 | CTU Triage Date: 30-01-2019 | Total Pages : 4

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman

Mfr. report#: US-JNJFOC-20180719747
Date of this report: 01/25/2019

B5. Describe Event or Problem (Cont...)

unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202.Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information.

This case is a duplicate of 20181013176. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 13-JAN-2019.

This report contains no new regulatory relevant information. No changes were made to the report.Additional medically important information was received on 13-JAN-2019.

The patient stated that, the product made people sick.
Senders Comments/Medical Assessment: ...

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

Lab Result:

Test Name	Test Date	Test Result	Normal High	Normal Low
BIOPSY	??/??/????	unknown		

G8. Adverse Event Term (Cont...)

2) PRODUCT FORMULATION ISSUE

CTU No.: FDA-CDER-CTU-2019-09792 | Department: CFSAN | RCT No.: RCT-408814 | CTU Triage Date: 14-06-2019 | Total Pages 4

JNJ Consumer US Cosmetic

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

MEDWATCH
3500A Facsimile

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

FDA Facsimile Approval: 01/30/2007

Mfr report #: US-JNJFOC-20180719747
UF/Importer report #:
FDA use only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	or 68 Years	[X] Female [ ] Male	lbs or kgs
In confidence	Date of Birth: ??/??/????		UNK

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [X] Product Problem *(e.g., defects/malfunctions)*

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
- [X] Other Serious *(Important Medical Events)*
- [ ] Required Intervention to Prevent Permanent Impairment/Damage(Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
??/??/????	06/12/2019

5. Describe Event or Problem

This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.

The patient's weight, height and medical history were unknown.

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified) for unknown indication. Concomitant medications

(Cont.)

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
No Relevant History Reported

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

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (OGX EVER STRAIGHTENING) Shampoo
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 Topical	#1 02/26/2017-??/??/????
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 PRODUCT USED FOR UNKNOWN INDICATION	#1 [ ] Yes [ ] No [ ] Doesn't Apply UNK
#2	#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 unknown	#1 ??/??/????	#1 [ ] Yes [ ] No [ ] Doesn't Apply UNK
#2	#2	#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*
No Concomitant Products Reported

D. 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

10. Device Available for Evaluation? *(Do not send to FDA)*
[ ] Yes [ ] No [ ] Returned to Manufacturer on: *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of Event)*

E. INITIAL REPORTER

1. Name & Address	Phone #
(b) (6) UNITED STATES	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
[ ] Yes [X] No	Unknown	[ ] Yes [ ] No [X] Unk

CTU No.: FDA-CDER-CTU-2019-69792 | Department: CFSAN | RCT No.: RCT-408814 | CTU Triage Date: 14-06-2019 | Total Pages : 4

JNJ Consumer US Cosmetic

MEDWATCH

3500A Facsimile *(Continued)*

FDA USE ONLY
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration
FDA Use Only

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ☐ No *(mm/dd/yyyy)*
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ☐ No *(mm/dd/yyyy)*
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

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

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman
UNITED STATES

2. Phone Number: 1 -60945594 02
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/01/2019
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(K)# ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ 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 # 3
8. Adverse Event Term(s): 1) CHEMICAL POISONING (Cont.)
9. Manufacturer Report Number: US-JNJFOC-20180719747

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and/or 11. ☐ Corrected Data

CTU No.: FDA-CDER-CTU-2019-69792 | Department: CFSAN | RCT No.: RCT-408814 | CTU Triage Date: 14-06-2019 | Total Pages : 4

B5. Describe Event or Problem (Cont...)

were not reported.

On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.

Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.

The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.

This report was associated with the product complaint and product complaint number was 30001451719.

This report was serious (medically significant).Follow up information was received on 15-JUL-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the reportFollow up information was received on 14-AUG-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Additional information was received on 30-AUG-2018.

This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was

CTU No.: FDA-CDER-CTU-2019-69792 | Department: CFSAN | RCT No.: RCT-408814 | CTU Triage Date: 14-06-2019 | Total Pages : 4

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman

Continuation Sheet for FDA-3500A Form

Mfr. report#: US-JNJFOC-20180719747
Date of this report: 06/12/2019

B5. Describe Event or Problem (Cont...)

unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202.Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information.

This case is a duplicate of 20181013176. Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 06-SEP-2018.

This report contains no new regulatory relevant information. No changes were made to the report.Follow up information was received on 13-JAN-2019.

This report contains no new regulatory relevant information. No changes were made to the report.Additional medically important information was received on 13-JAN-2019.

The patient stated that, the product made people sick.Additional medically important information was received from patient on 01-JUN-2019.

On an unspecified date, patient developed formaldehyde poisoning and formaldehyde cancer (chemical poisoning) due to which she was getting sicker and sicker. Patient mentioned that formaldehyde got into her gum skin, eyes, nose, mouth, ears and bones. It was not going away and was affecting her health. The event of chemical poisoning and cancer did not resolve.
Senders Comments/Medical Assessment: ...

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

Lab Result:

Test Name	Test Date	Test Result	Normal High	Normal Low
BIOPSY	??/??/????	unknown		

G8. Adverse Event Term (Cont...)

2) PRODUCT FORMULATION ISSUE

CTU No.: FDA-CDER-CTU-2020-7931 | Department: CFSAN | RCT No.: RCT-708891 | CTU Triage Date: 22-01-2020 | Total Pages: 4

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-20180719747

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: [X] Year(s) [ ] Month(s) [ ] Week(s) [ ] Day(s) 68 or Date of Birth (e.g., 08 Feb 1925): (b) (6)
3. Sex: [X] 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. [X] 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
[X] 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): 21-Jan-2020

5. Describe Event or Problem
This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media; 000311323.
The patient's weight, height and medical history were unknown.
Continued

6. Relevant Tests/Laboratory Data, Including Dates
On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown.
Continued

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

4. Therapy Dates (If unknown give duration) from/to (or best estimate)) (dd-mmm-yyyy)
#1 26-Feb-2017 -
#2

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

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

10. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] Doesn't apply
#2 [ ] Yes [ ] No [X] 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
[X] Consumer
[ ] Health Professional
[ ] User Facility
[ ] Company Representative
[ ] Distributor
[ ] Other

4. Date Received by Manufacturer (dd-mmm-yyyy): 05 Jan 2020

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

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
[ ] 5-day [X] 30-day
[ ] 7-day [ ] Periodic
[ ] 10-day [ ] Initial
[ ] 15-day [X] Follow-up # 7

Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC [ ] Yes

8. Manufacturer Report Number: 20180719747

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

E. INITIAL REPORTER

1. Name and Address Continued
Last Name: (b) (6) First Name: (b) (6)
Address: 555 veazie st 108
City: (b) (6) State/Province/Region: (b) (6)
Country: USA ZIP/Postal Code: (b) (6)
Phone #: Email: (b) (6)

2. Health Professional? [ ] Yes [X] No

3. Occupation: Patient

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

CTU No.: FDA-CDER-CTU-2020-7931 | Department: CFSAN | RCT No.: RCT-768891 | CTU Triage Date: 22-01-2020 | Total Pages: 4

B. ADVERSE EVENT OR PRODUCT PROBLEM

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

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386)(topical, dose and frequency unspecified) for unknown indication. Concomitant medications were not reported.
On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.
Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.
The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.
This report was associated with the product complaint and product complaint number was 30001451719.
This report was serious (medically significant).

Follow up information was received on 15-JUL-2018.
This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018.
This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Additional information was received on 30-AUG-2018.
This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information.
This case is a duplicate of 20181013176.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the

CTU No.: FDA-CDER-CTU-2020-7931 | Department: CFSAN | RCT No.: RCT-768891 | CTU Triage Date: 22-01-2020 | Total Pages: 4

report.

Follow up information was received on 13-JAN-2019.
This report contains no new regulatory relevant information. No changes were made to the report.

Additional medically important information was received on 13-JAN-2019.
The patient stated that, the product made people sick.

Additional medically important information was received from patient on 01-JUN-2019.
On an unspecified date, patient developed formaldehyde poisoning and formaldehyde cancer (chemical poisoning) due to which she was getting sicker and sicker. Patient mentioned that formaldehyde got into her gum skin, eyes, nose, mouth, ears and bones. It was not going away and was affecting her health. The event of chemical poisoning and cancer did not resolve.

Additional medically important information was received from patient on 15-AUG-2019.
It was determined that Manufacturer Report Number 20190820522 was a duplicate of this case. All relevant information regarding this case will be submitted under Manufacturer Report Number 20180719747.
The following information was updated and incorporated into the case: The patient demographics were updated. It was reported that 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 patient had not recovered from hair loss and formaldehyde pockets in gums and the outcome of product label issue was unknown.

Additional information was received from patient on 15-JUL-2019. The following information was updated and incorporated into the case:
The reporter details were updated.

Additional information received from consumer on 27-SEP-2019. Upon review the following information were amended: On an unspecified date, the patient experienced redness on skin, blurriness and watering of the eyes, sores in mouth, infection of ears, nose, throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, snapping and rotting out of product from whole body (application site reaction), damaged skin and bones with swelling pain.
The patient had not recovered from redness on skin, blurriness and watering of the eyes, sores in mouth, infection of ears, nose throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, damaged skin and bones with swelling pain and the outcome of snapping and rotting out of product from whole body (application site reaction) was unknown.
The DC/RC was updated from unknown to not applicable for (chemical poisoning, formaldehyde pockets in gums, bumps on body and cracks in head and product snapping and rotting out of whole body) . The DC/RC captured as unknown for mouth sores. The event of product quality complaint removed from case.
This case is duplicate of 20190939051, 20190623129, 20180125792, 20180902554, 20181202118, 20181217921, 20181113853, 20190609048, 20190821504, 20180133420, 20181117366, 20181216775, 20190822079, 20181013667, 20190626249, 20190701083 and 20180102688.

Version created to amend previously reported information on 27-SEP-2019. Upon review the following information were amended in narrative: The DC/RC captured as unknown for hair loss, bumps on body and cracks in head and product snapping and rotting out of whole body.

Additional information was received from patient on 05-JAN-2020. The following information was updated and incorporated into the case narrative:
On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED (topical, dose and frequency unspecified) for unknown indication.
Patient reported that, she had over exposed to formaldehyde and was slowly poisoning herself in and out and all her hair is rotting out of her scalp and body and it made her sick after using the products. It was reported that the patient was experiencing the events from three years and she was still sick and going bald.
Action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED was unknown.
This case involving the the same patient was linked to case 20200111795.

Company Remarks :

...

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

Lab Result :

Test name	Test date	Test result	Normal value	Classification
BIOPSY		unknown		

CTU No.: FDA-CDER-CTU-2020-7931 | Department: CFSAN | RCT No.: RCT-768891 | CTU Triage Date: 22-01-2020 | Total Pages: 4

(Biopsy)

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

Seq No. : 1
C.1 Suspect Product : OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ
C.9 Dechallenge : 2) N/A
: 3) UNK
: 4) UNK
: 5) UNK
: 6) UNK

C.10 Rechallenge : 2) N/A
: 3) UNK
: 4) UNK
: 5) UNK
: 6) UNK

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

C.10 Rechallenge : 2) N/A
: 3) UNK
: 4) UNK
: 5) UNK
: 6) UNK

E. INITIAL REPORTER (Cont...)

State: Rhode Island
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) CHEMICAL POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
2) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))
3) HAIR LOSS (Application site alopecia (10059046), Application site alopecia (10059046))
4) MOUTH SORES (Sores mouth (10049318), Stomatitis (10042128))
5) BUMPS ALL OVER BODY (Application site papules (10049043), Application site papules (10049043))
6) CRACKS IN HEAD AND PRODUCT SNAPPING AND ROTTING OUT OF WHOLE BODY (Application site reaction (10003055), Application site reaction (10003055))

CTU No.: FDA-CDER-CTU-2020-24824 | Department: CFSAN | RCT No.: RCT-780282 | CTU Triage Date: 02-03-2020 | Total Pages: 4

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-20180719747

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: [X] Year(s) [ ] Month(s) [ ] Week(s) [ ] Day(s) — 68
or Date of Birth (e.g., 08 Feb 1925): (b) (6)

3. Sex: [X] 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. [X] 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
[X] 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): 28-Feb-2020

5. Describe Event or Problem
This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.
The patient's weight, height and medical history were unknown.
Continued

6. Relevant Tests/Laboratory Data, Including Dates
On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown.
Continued

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#
	unknown
#2 - Name and Strength	#2 - NDC # or Unique ID
OGX EVER Continued	
#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		Topical

4. Therapy Dates (If unknown give duration) from/to (or best estimate) (dd-mmm-yyyy)
#1 26-Feb-2017 -
#2

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

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

10. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] Doesn't apply
#2 [ ] Yes [ ] No [X] 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
[X] Consumer
[ ] Health Professional
[ ] User Facility
[ ] Company Representative
[ ] Distributor
[ ] Other

Compounding Outsourcing Facility 503B? [ ] Yes

4. Date Received by Manufacturer (dd-mmm-yyyy): 19-Feb-2020

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

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
[ ] 5-day [X] 30-day
[ ] 7-day [ ] Periodic
[ ] 10-day [ ] Initial
[ ] 15-day [X] Follow-up # 5

Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC [ ] Yes

8. Manufacturer Report Number: 20180719747

8. Adverse Event Term(s)
1) CHEMICAL 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: (b) (6)
Phone #: Email: (b) (6)

2. Health Professional? [ ] Yes [X] 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...)

On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386)(topical, dose and frequency unspecified) for unknown indication. Concomitant medications were not reported.
On an unspecified date, the patient experienced toxically poisoned body (chemical poisoning) due to the chemicals in the product (product ingredient issue). The patient reported that it was getting worse like a bronzeing cancer going through whole body.
Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 13OZ(EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) was unknown.
The outcome was unknown for toxically poisoned body (chemical poisoning) and product ingredient issue.
This report was associated with the product complaint and product complaint number was 30001451719.
This report was serious (medically significant).

Follow up information was received on 15-JUL-2018.
This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018.
This report contains no new regulatory relevant information. No changes were made to the report

Follow up information was received on 14-AUG-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Additional information was received on 30-AUG-2018.
This report concerns a 68 year old female patient. On 26-FEB-2017, the patient started using OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (topical, dose and frequency unspecified) to condition her hair. The patient concomitantly used Pantene Conditioner as a conditioner. On an unspecified date, the patient reported that usage of product toxically poisoned her body (chemical poisoning) due to dangerous chemicals in the product (product ingredient issue). Because of chemical poisoning her hair were melt, fry, dry, frizzy, brittle which started to break, injured. On an unspecified date, since 11 months prior to report she also noticed that her head hair, eyelashes, eyebrows were falling and ruined her scalp. She experienced burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body. The patient reported that product ruined her life. The patient also noticed that her hair turned into one sometime two knots due to which she cannot even wash her hair and it was snapping out of her head. She also mentioned that her leg's and eyebrows hair were gone and she had blond hair, turning into burnt brown. She was not able to dye her hair either because it made her hair feel like a rubber band. She also stated that her situation was getting worse like a bronzing cancer going through whole body. She could feel her body trying to fight the poison every day. The patient also developed cracked skin and feet. She noticed that her hair growth stunted and her skin was turning into plastic. She reported that the product did not even had child proof cap and it was toxic. The patient stated that she could feel pressure in her body and head as all events happened to her and she was trying to heal from it. On an unspecified date, the physician was consulted and she had a biopsy done on her scalp, results unknown. The patient used Preallergy shampoo to treat the events. Patient had long, black and flowing hair to her belly button that was bouncy and long. The outcome of events fried hair, dry hair, brittle hair which broke, knotted hair, hair feels like rubber band, loss of hair, injured hair, blonde hair, hair turning into burnt brown, skin turned into plastic, cracked skin and feet, burning eyes, burning sensation on her scalp skin, in eyes, eyebrows eyelashes and body, dry skin, stunted hair growth (chemical poisoning) and product ingredient issue was unknown. This case is a duplicate of 20180719747, 20180902554, 20180102688, 20171108730, 20171120957, 20180324707, 20180828488, 20180901076, 20180903071 and 20180724202.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018. This report contains no new regulatory relevant information.
This case is a duplicate of 20181013176.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the report.

Follow up information was received on 06-SEP-2018.
This report contains no new regulatory relevant information. No changes were made to the

report.

Follow up information was received on 13-JAN-2019.
This report contains no new regulatory relevant information. No changes were made to the report.

Additional medically important information was received on 13-JAN-2019.
The patient stated that, the product made people sick.

Additional medically important information was received from patient on 01-JUN-2019.
On an unspecified date, patient developed formaldehyde poisoning and formaldehyde cancer (chemical poisoning) due to which she was getting sicker and sicker. Patient mentioned that formaldehyde got into her gum skin, eyes, nose, mouth, ears and bones. It was not going away and was affecting her health. The event of chemical poisoning and cancer did not resolve.

Additional medically important information was received from patient on 15-AUG-2019.
It was determined that Manufacturer Report Number 20190820522 was a duplicate of this case. All relevant information regarding this case will be submitted under Manufacturer Report Number 20180719747.
The following information was updated and incorporated into the case: The patient demographics were updated. It was reported that 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 patient had not recovered from hair loss and formaldehyde pockets in gums and the outcome of product label issue was unknown.

Additional information was received from patient on 15-JUL-2019. The following information was updated and incorporated into the case:
The reporter details were updated.

Additional information received from consumer on 27-SEP-2019. Upon review the following information were amended: On an unspecified date, the patient experienced redness on skin, blurriness and watering of the eyes, sores in mouth, infection of ears, nose, throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, snapping and rotting out of product from whole body (application site reaction), damaged skin and bones with swelling pain.
The patient had not recovered from redness on skin, blurriness and watering of the eyes, sores in mouth, infection of ears, nose throat and skin on whole body, swelling of body, cracks in head (application site reaction), burning in head, stomach sickness, ear burning, nose burning, throat burning, bumps and numbness on whole body, hair turned white, swelling on head, eyes, nose, mouth, gums, neck, ears and cheeks, damaged skin and bones with swelling pain and the outcome of snapping and rotting out of product from whole body (application site reaction) was unknown.
The DC/RC was updated from unknown to not applicable for (chemical poisoning, formaldehyde pockets in gums, bumps on body and cracks in head and product snapping and rotting out of whole body) . The DC/RC captured as unknown for mouth sores. The event of product quality complaint removed from case.
This case is duplicate of 20190939051, 20190623129, 20180125792, 20180902554, 20181202118, 20181217921, 20181113853, 20190609048, 20190821504, 20180133420, 20181117366, 20181216775, 20190822079, 20181013667, 20190626249, 20190701083 and 20180102688.

Version created to amend previously reported information on 27-SEP-2019. Upon review the following information were amended in narrative: The DC/RC captured as unknown for hair loss, bumps on body and cracks in head and product snapping and rotting out of whole body.

Additional information was received from patient on 05-JAN-2020. The following information was updated and incorporated into the case narrative:
On an unspecified date, the patient started using OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED (topical, dose and frequency unspecified) for unknown indication.
Patient reported that, she had over exposed to formaldehyde and was slowly poisoning herself in and out and all her hair is rotting out of her scalp and body and it made her sick after using the products. It was reported that the patient was experiencing the events from three years and she was still sick and going bald.
Action taken with OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED was unknown.
This case involving the the same patient was linked to case 20200111795.

Additional information was received from patient on 19-FEB-2020. The following information was updated and incorporated into the case narrative:
The patient reported that, she was not using the products from three years and the events were not going away and was spreading. All the bones and soft tissues in her face, neck, head, throat, ears, eyes, nose and mouth are swelling and in pain and all her hair got rotted off from her whole body and it was all rotting out of her scalp permanently from over exposure to toxic formaldehyde poisoning. The patient reported that she had to visit the hospital and to physician every day for the treatment.
On an unspecified, the OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ (OGX BEAUTY EVER STRINGHTNER BRIZILAN KERATIN THERAPY CONDITIONER) and OGX EVER STRAIGHTENING BRAZILIAN KERATIN THERAPY SHAMPOO UNSPECIFIED was withdrawn.
This case involving the same patient was linked to case 20200238115.

Company Remarks :

...

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

Lab Result :

Test name	Test date	Test result	Normal value	Classification
BIOPSY (Biopsy)		unknown		

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

Seq No. : 1
C.1 Suspect Product : OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 13OZ
C.9 Dechallenge : 2) N/A
: 3) UNK
: 4) UNK
: 5) UNK
: 6) UNK

C.10 Rechallenge : 2) N/A
: 3) UNK
: 4) UNK
: 5) UNK
: 6) UNK

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

C.10 Rechallenge : 2) N/A
: 3) UNK
: 4) UNK
: 5) UNK
: 6) UNK

E. INITIAL REPORTER (Cont...)

State: Rhode Island
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) CHEMICAL POISONING (Chemical poisoning (10008428), Chemical poisoning (10008428))
2) FORMALDEHYDE POCKETS IN GUMS (Gum disorder (10018775), Gingival disorder (10018280))
3) HAIR LOSS (Application site alopecia (10059046), Application site alopecia (10059046))
4) MOUTH SORES (Sores mouth (10049318), Stomatitis (10042128))
5) BUMPS ALL OVER BODY (Application site papules (10049043), Application site papules (10049043))
6) CRACKS IN HEAD AND PRODUCT SNAPPING AND ROTTING OUT OF WHOLE BODY (Application site reaction (10003055), Application site reaction (10003055))

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	High		
FDA Received Date	11-Aug-2018	CTU Received Date	11-Aug-2018
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	11-Aug-2018
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident
	Other serious/important medical incident	

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

I got a Brazilian blowdry treatment on my hair and the salon stylist used a product on me that mainly contained methylene glycol.As soon as the procedure began I had redness in my eyes and my eyes started watering profusely.My head started hurting and my skin developed itchiness.I also felt an extreme irritation in my nostrils and the symptoms have not stopped even though it has been 2 hours post treatment.I also experienced bronchoconstruction and could not swallow food for some time.This was the worst adverse reaction I have ever encountered.

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

Section B - About the Products 1 of 1

	Suspect	Yes		
	Primary?	Yes		
	Product Type	Drug/Biologic		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Açaí Professional Brazilian Blowout solution		
	Name of the company that makes (or compounds) the product	METHYLENE GLYCOL		
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	Yes		
	Is the Product Over-the-Counter?	Yes		
	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		
	Do you still have the product in case we need to evaluate it?	Yes		
	Returned to Manufacturer Date			

Drug Therapy 1 of 1

	Expiration date			
	Lot number			
	Dosage Form			
	Quantity	Other	If Other	6 Puff(s)
	Frequency		If Other	
	How was it taken or used	Topical	If Other	
	Date the person first started taking or using the product	11-Aug-2018		
	Date the person stopped taking or using the product	11-Aug-2018		
	Therapy Duration			
	Therapy Ongoing ?			

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

	Cosmetic treatment for the hair

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	26 Year(s)
Date of Birth	
Weight	62.1 kg(s)
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)

None

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

None

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

None

List all current prescription medications and medical devices being used.

None

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

None

Section E - 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	11-Aug-2018
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		
FDA Received Date	16-Aug-2018	CTU Received Date	16-Aug-2018
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	28-Jul-2014
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident
Other serious/important medical incident	Trouble breathing

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

Got a brazilian keratin treatment done to smooth out the texture of my hair. During the treatment I could not breathe properly, I would cough, and my eyes stung. I was offered a wet towel and it relieved my symtoms.sensation during styling or when it got close to my eyes. Following the treatment I had triuble breathing and oftwn timws felt a burning sensation in my lungs, nose, and eyes for a week. I also had a lot of dandruff and oilt scalp as I had not before.

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

N/A

Section B - About the Products 1 of 1

	Suspect	Yes
	Primary?	Yes
	Product Type	Drug/Biologic
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Clear reconstructor solution
	Name of the company that makes (or compounds) the product	Pure brazilian
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	
	Is the Product Over-the-Counter?	
	Strength	If Other
	NDC number	
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No
	Did the problem return if the person started taking or using the product again?	Doesn't Apply
	Do you still have the product in case we need to evaluate it?	No
	Returned to Manufacturer Date	

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	
	Therapy Duration	1 Day
	Therapy Ongoing ?	

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

	Improve hair texture

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	22 Year(s)
Date of Birth	
Weight	
Ethnicity (Choose only one)	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)

NA

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

NA

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

NA

List all current prescription medications and medical devices being used.

NA

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

NA

Section E - 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	USA
ZIP or Postal code	
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	16-Aug-2018
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		
FDA Received Date	09-Aug-2018	CTU Received Date	09-Aug-2018
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	04-Aug-2018
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident
	Other serious/important medical incident	fever, cough, burning eyes,

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

My daughter (14), had a Brazillion blowout hair treatment done at a salon. Within 72 hours, she began coughing, her eyes were burning, her nose was running, She began to feel dizzy and her head started hurting. Her Dr. couldn't diagnose her with anything but put her on an antibiotic on 8/5. It is now one week after the treatment and she still has 100.5 temp. with a cough. No one around her has gotten sick within 7 days.

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

Section B - About the Products 1 of 1

	Suspect	Yes	
	Primary?	Yes	
	Product Type	Drug/Biologic	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazillion Blowout Hair Treatnebt	
	Name of the company that makes (or compounds) the product		
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		
	Is the Product Over-the-Counter?		
	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?	No	
	Do you still have the product in case we need to evaluate it?	No	
	Returned to Manufacturer Date		

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		
	Therapy Duration		
	Therapy Ongoing ?		

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

	hair smoothing treatment

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	
Date of Birth	(b) (6)
Weight	56.25 kg(s)
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)

none

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

none

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

no health problems ircallergies

List all current prescription medications and medical devices being used.

amoxicillin -tobtreat symptoms

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

none

Section E - 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	09-Aug-2018
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		
FDA Received Date	22-Aug-2018	CTU Received Date	22-Aug-2018
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	21-Aug-2018
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident

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

I had a Brazilian blowout hair straightening treatment at a salon. My eyes and throat were burning pretty bad during the treatment. When I went home I was so dizzy and had a headache and went to sleep for maybe 12 hours. I woke up the next day and I still have a headache and feel fatigue, and my nose is still burning too.

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

N/A

Section B - About the Products 1 of 1

Suspect	Yes
Primary?	Yes

	Product Type	Drug/Biologic	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian Blowout	
	Name of the company that makes (or compounds) the product	Don't know	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		
	Is the Product Over-the-Counter?		
	Strength	If Other	
	NDC number		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No	
	Did the problem return if the person started taking or using the product again?	Doesn't Apply	
	Do you still have the product in case we need to evaluate it?	No	
	Returned to Manufacturer Date		

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		
	Therapy Duration		
	Therapy Ongoing ?		

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

	Hair straightening treatment

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)

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

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

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

Section D - About the Person Who Had the Problem

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

N/A

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

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

List all current prescription medications and medical devices being used.

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

Section E - 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	USA
ZIP or Postal code	
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	22-Aug-2018
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		
FDA Received Date	24-Aug-2018	CTU Received Date	24-Aug-2018
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	22-Aug-2018
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident
Other serious/important medical incident	Asthma attack

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

Had a hair cut at (b) (4) . a spray product called "Regis Enchanted Midnight leave in with Keratin" was sprayed onto my hair. The fragrance in this product caused a serious allergic reaction and asthma which required the use of antihistamines and inhaler for more than a day. The fragrance was very persistant and could not be completely removed even after 6 shampooings. I do not have the container for this product since it is owned by the salon.

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

Section B - About the Products 1 of 1

	Suspect	Yes	
	Primary?	Yes	
	Product Type	Drug/Biologic	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Enchanted Midnight leave in with keratin	
	Name of the company that makes (or compounds) the product	Regis	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		
	Is the Product Over-the-Counter?	Yes	
	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	
	Do you still have the product in case we need to evaluate it?	No	
	Returned to Manufacturer Date		

Drug Therapy 1 of 1

	Expiration date		
	Lot number		
	Dosage Form		
	Quantity	If Other	
	Frequency	If Other	
	How was it taken or used	Topical	If Other
	Date the person first started taking or using the product	22-Aug-2018	
	Date the person stopped taking or using the product	22-Aug-2018	
	Therapy Duration		
	Therapy Ongoing ?		

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

	Part of salon treatment

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	33 Year(s)
Date of Birth	
Weight	58.5 kg(s)
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)

Ashtma, hypothyroidism

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

Pollen, cats, some fragrances

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.

Synthroid

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

None

Section E - 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	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	24-Aug-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity disclosed to the manufacturer, 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		
FDA Received Date	26-Aug-2018	CTU Received Date	26-Aug-2018
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	24-Aug-2018
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident

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

Reaction to Brazilian blowout. Tight chest, burning nose and throat stinging watery eyes and headache

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

It contains formaldehyde when heated and is known to cause cancer

Section B - About the Products 1 of 1

Suspect	Yes
Primary?	Yes

	Product Type	Drug/Biologic		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian blowout		
	Name of the company that makes (or compounds) the product	Brazilian blowout		
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
	Is the Product Over-the-Counter?			
	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?			
	Do you still have the product in case we need to evaluate it?	Yes		
	Returned to Manufacturer Date			

Drug Therapy 1 of 1

	Expiration date			
	Lot number			
	Dosage Form			
	Quantity		If Other	
	Frequency		If Other	
	How was it taken or used	Other	If Other	product is flat ironed into the hair
	Date the person first started taking or using the product			
	Date the person stopped taking or using the product			
	Therapy Duration			
	Therapy Ongoing ?			

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

	Hair straightener

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	36 Year(s)
Date of Birth	
Weight	65.25 kg(s)
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)

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 E - 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	26-Aug-2018
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		
FDA Received Date	01-Oct-2018	CTU Received Date	01-Oct-2018
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	29-Sep-2018
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident

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

I need to report a reaction I am having from the Brazilain Blowout treatment. I had this done on Saturday October 29, the person who did the treatment on me kept applying it directly to my scalp, which is not supposed to be down. 2 hours later I felt dizzy, now it is 3 days later and I feel unbalanced, dizzy, slurred speech., these chemicals have aborded into my head and I am having severe nuerological issues

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

Section B - About the Products 1 of 1

Suspect	Yes
Primary?	Yes

	Product Type	Drug/Biologic	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian Blowout	
	Name of the company that makes (or compounds) the product	Brazilian Blowout	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		
	Is the Product Over-the-Counter?		
	Strength	If Other	
	NDC number		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No	
	Did the problem return if the person started taking or using the product again?		
	Do you still have the product in case we need to evaluate it?	No	
	Returned to Manufacturer Date		

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	29-Sep-2018	
	Date the person stopped taking or using the product		
	Therapy Duration		
	Therapy Ongoing ?		

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

	to smooth hair

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	39 Year(s)
Date of Birth	
Weight	60.75 kg(s)
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)

none

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

none

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

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 E - 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	01-Oct-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity disclosed to the manufacturer, 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		
FDA Received Date	11-Oct-2018	CTU Received Date	11-Oct-2018
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	26-Sep-2018
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident

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

I used the Cezanne Smoothing Treatment on a client. It promises to have no odor, no smell, no formaldehyde, and be made from natural ingredients. After applying the product to the clients hair, there was a very strong smell. I then got an immediate headache and my chest felt tight and heavy. I needed to leave the room. The physical response I had was similar to one you would have to a product containing formaldehyde.

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

I researched the chemicals in the product and also had a chemist analyze them and found out that galoxyloyl carbocysteine is an aldehyde.

Section B - About the Products 1 of 1

Suspect	Yes
Primary?	Yes

	Product Type	Drug/Biologic	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Cezanne Classic Keratin Smoothing Treatment	
	Name of the company that makes (or compounds) the product	Cezanne	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		
	Is the Product Over-the-Counter?		
	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?		
	Do you still have the product in case we need to evaluate it?	No	
	Returned to Manufacturer Date		

Drug Therapy 1 of 1

	Expiration date	01-Jan-2019	
	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		
	Therapy Duration		
	Therapy Ongoing ?		

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

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	36 Year(s)
Date of Birth	
Weight	58.5 kg(s)
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)

none

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

penicillin

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.

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

Section E - 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	USA
ZIP or Postal code	
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	11-Oct-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity disclosed to the manufacturer, 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		
FDA Received Date	15-Oct-2018	CTU Received Date	15-Oct-2018
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	13-Oct-2018
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident

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

I was working in my salon on Saturday while one of my coworkers was performing a Brazilian Blowout. Now I am having chest pains and trouble breathing... my symptoms are gradually getting better, now it's more of a stinging, raw feeling in my lungs.

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

Section B - About the Products 1 of 1

Suspect	Yes
Primary?	Yes

	Product Type	Drug/Biologic	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazillian Blowout smoothing system	
	Name of the company that makes (or compounds) the product	Brazilian Blowout	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		
	Is the Product Over-the-Counter?		
	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?		
	Do you still have the product in case we need to evaluate it?	Yes	
	Returned to Manufacturer Date		

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	13-Oct-2018	
	Date the person stopped taking or using the product		
	Therapy Duration		
	Therapy Ongoing ?		

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

	Smoothing hair

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)

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

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

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

Section D - About the Person Who Had the Problem

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

Hypothyroidism hashimotos

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

Pollen

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.

Unithroid

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

Multi vitamin magnesium

Section E - 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	15-Oct-2018
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	High		
FDA Received Date	05-Nov-2018	CTU Received Date	06-Nov-2018
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)			

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	04-Nov-2018
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident
Other serious/important medical incident	

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

I purchased Arganatural de keratina smoothing shampoo and conditioner at CVS. Had to continually pump to get lather going Rinsed then used the conditioner. I had an immediate reaction of dryness and could not get the conditioner to rinse off. It created a dehydration on my lips and saliva glands dryness. When I licked it. I would like to know what was in this product to cause this reaction.I would like to know what caused this reaction please , Never in my life had this awful experience. Thank you.

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

Section B - About the Products 1 of 1

	Suspect	Yes	
	Primary?	Yes	
	Product Type	Drug/Biologic	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	de keratia smoothing shampoo and de keratina smoothing conditioner	
	Name of the company that makes (or compounds) the product	Arganatural	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	Yes	
	Is the Product Over-the-Counter?	Yes	
	Strength	If Other	
	NDC number		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No	
	Did the problem return if the person started taking or using the product again?	Doesn't Apply	
	Do you still have the product in case we need to evaluate it?	Yes	
	Returned to Manufacturer Date		

Drug Therapy 1 of 1

	Expiration date		
	Lot number		
	Dosage Form		
	Quantity	If Other	
	Frequency	If Other	
	How was it taken or used	Topical	If Other
	Date the person first started taking or using the product	04-Nov-2018	
	Date the person stopped taking or using the product	05-Nov-2018	
	Therapy Duration		
	Therapy Ongoing ?		

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

	Shampoo and conditioner treatment

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	55 Year(s)
Date of Birth	
Weight	
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)

Diabetes

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

None

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

N/A

List all current prescription medications and medical devices being used.

N/A

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

N/A

Section E - 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	
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	05-Nov-2018
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		
FDA Received Date	11-Nov-2018	CTU Received Date	11-Nov-2018
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)	

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	05-Nov-2018
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☑ Life-threatening ☐ Death ☐ Other serious/important medical incident

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

My wife uses Brazilian Blowout at work. After an especially long day ay work, she came home feeling very sick. Usually comes home with headaches and trouble breathing. This time she vomited blood on two occasions. It is of my understanding that Brazilian Blowout is unregulated. The formaldehyde is killing my wife, I'm sure of it. Please ban this poison!

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

Section B - About the Products 1 of 1

Suspect	Yes

	Primary?	Yes	
	Product Type	Drug/Biologic	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian Blowout	
	Name of the company that makes (or compounds) the product	Brazilian Blowout	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)		
	Is the Product Over-the-Counter?	Yes	
	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	
	Do you still have the product in case we need to evaluate it?	Yes	
	Returned to Manufacturer Date		

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		
	Therapy Duration		
	Therapy Ongoing ?		

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

	Work

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	
Date of Birth	21-May-1987
Weight	60 kg(s)
Ethnicity (Choose only one)	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)

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 E - 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	USA
ZIP or Postal code	
Telephone number	
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	11-Nov-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

Begin a Voluntary Report / Initial Report

Introduction

Report Title

CFSAN CAERS PHONE REPORT 10/21/2019

Did the food or product make someone sick, cause a negative reaction, or some other health problem?

Yes

Was there a problem with the product (e.g., defect in the product such as an unusual odor, taste, or appearance)?

Yes

Reporter Information

Do you wish to remain anonymous to the FDA?

No

First Name	**Last Name**
(b) (6)	(b) (6)

Primary Phone

(b) (6)

Mail/Zip Code	**Country**
00000	United States

What is your relationship to the individual affected? The affected individual is your:

I am the affected person

Suspect Product

Product Type	**Product Name**
Cosmetic	OGX BRAZILIAN THERAPY STRAIGHTENING CONDITIONER

Affected Individual

Gender	**Age at the time of event**
Female	0 year(s) old

Adverse Event

Outcomes attributed to this adverse event

Other serious/important medical incident

Description of adverse event.

This product is banned in canada. OGX BRAZILIAN THERAPY STRAIGHTENING CONDITIONER. I have formaldehyde poisoning. Others can get sick from this. There are no warnings on the bottles. The FDA sent out a complaint to salons about improper directions in 2011 and is over the limit. Nothing is being done about this and it needs to be removed from the market. I am still sick. This does not belong in the

public. It belongs in the salon where it can be properly used. This is supposed to be taken off the shelf this month and I am not sure why it is not and is still being sold in stores. I have beautiful hair. All my hair has fallen off. I sent pictures of my hair coming out. The EWG is trying to get it off the shelves and FDA is ignoring them. Environmental Womens Group. This effected my gums and tongue and the dentist know its not my teeth. They are telling me it is something else. Formaldehyde is not treatable because they cannot find it. That is how they get away with it. The damages you get from it can't be found. So nothing can be treated. You can get formaldehyde cancer from this. I can't believe what I was reading about this stuff I was putting on my body. The company lied and said it is formaldehyde free and it wasn't and had improper directions on the label. It is supposed to be used once a year by a professional and I was using it once a day like a conditioner. This has been going on for years. I am not sure why it is still going on and is still on the market. The hair came right off my body. ALL of my hair came off and has been going on for almost three years now. I bought this product in 2013 and was using it on and off. I got the issues and got sick, and didn't realize it was this product until I read about this online. It melted my hair like plastic. The symptoms started getting worse and worse. Couldn't believe it was a hair product that did this. Very bad fatigue. My hair is rotting out of my scalp. Turns white then a brown color and falls out of my body. This is a toxic chemical. The FDA has gotten these complaints years ago in 2006, 2011 warnings out to salons. I bought mine in 2013 and would never have bought it if it had been of the shelves. I had long beautiful hair and it is now gone. I sent pictures. The bones in my nose, cheeks have bumps all inside - sores due to this product exposure. Everything I read actually happened to me. This is banned in canada, you can't even buy it in canada. There is a Chinese product similar that you can't buy, but this brazilian product can be still bought on the market. When I started getting symptoms like that, the doctors couldn't find anything. And I realized it was this product. I looked up the FDA reviews/reports on this and I realized it was this product making me sick. I used a whole bottle, and was going to use another one - the second bottle, my hair had turned to plastic and this is what is making me sick. You don't realize that a hair product could do this. The horrible symptoms are coming from this product. I have medical records that can be provided for this issue. Fatigue and facial, neck swelling. Slowly poisoning yourself. I stopped product use but the symptoms are still ongoing. It will have been 3 years no since product discontinue and I am still having symptoms. Swelling and lumps in my nose and head and my hair is destroyed. This product belongs off the market immediately. They are selling salon professional products to the public. There are no directions on the label regarding product use for the public. No notification or warnings of formaldehyde ingredients in the product. I called Johnson and Johnson and reported it. They sent me papers to fill out, but I have not completed them. I am afraid to use anything since I got sick from this. Once you have poisoned by a product, it changes your whole life. Headaches, swollen head, people think i am crazy but when I showed my doctor the stuff I was using - he believed everything I said. I had all kinds of tests due to this product use. The formaldehyde was getting into my soft tissue. The Environmental Women's Group is trying to get this product off the shelf.

Signs, Symptoms, or Diagnoses

Product Problem Description

Attachment

Document Type

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	14-Dec-2018	CTU Received Date	14-Dec-2018
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)

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	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident

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

CFSAN CAERS PHONE REPORT: My name is (b) (6) I am calling to report a Formaldehyde Poisoning, from the Brazilian Everstraight Keratine Therapy conditioner. I have called you before. Thigns are getting worse. I am very sick from this. i have no idea how to fix this. I am toxically poisoned by formaldehyde. I have been using it for three years following directions on this bottle. There was a warning out in 2011 about how dangerous this product was from Orpholon. These directions are not proper directions for consumer use. This is not an everyday conditioner, it is a treatment product and should be used every twelve months. I didn't know that, and was using it once a week. I had a biopsy. i feel very sick. i have all signs of formaldehyde poisoning. hair growth stunted. my skin is profusely dry, no oils, effected my eyes, my whole body. my breathing. i am going to end up in a hospital. i need to know what to do.

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

Section B - About the Products 1 of 1

	Suspect	Yes
	Primary?	Yes
	Product Type	Drug/Biologic
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Brazilian Everstraight Keratine Therapy conditioner
	Name of the company that makes (or compounds) the product	
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	
	Is the Product Over-the-Counter?	
	Strength	If Other
	NDC number	
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No
	Did the problem return if the person started taking or using the product again?	
	Do you still have the product in case we need to evaluate it?	
	Returned to Manufacturer Date	

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	
	Therapy Duration	
	Therapy Ongoing ?	

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

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)

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

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

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

Section D - About the Person Who Had the Problem

Person's Initials	Unspecified
Sex	
Age (specify unit of time for age)	
Date of Birth	
Weight	
Ethnicity (Choose only one)	
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)

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 E - 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	USA
ZIP or Postal code	
Telephone number	(b) (6)
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	14-Dec-2018
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	12-Apr-2019	CTU Received Date	12-Apr-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	18-Jan-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)

Keratin treatment / Product- Keratin Complex. (https://www.keratincomplex.com) Jan 18th, 2019. Next day i wake up to a rash all along my hairline, face and neck, looked like chemical burns. Stylist swore no Formaldehyde. Each time I washed hair, blow dried and used flat iron, rash would come back. I figured I was allergic to something else in it. Fast forward to March 2019, I am still getting the rash when I apply heat to my hair. Nose Bleeds. TONS of hair breakage. On April 5th, I am now seeing a pulmonologist for difficulty in breathing, heavy tight chest. I am on two different asthma inhalers. Finally asked my stylist for a list of ingredients. Boom, there it is- Timonacic... when heated such as for these treatments it turns into Formaldehyde. It wrecks HAVOC on skin and lungs. This is why every time I would wash, blow dry and flat iron my hair the rash would come back, heat brings it alive again. Chest Xray next week to see how much damage it has done to my pulmonary system, I am devastated. These companies LIE!!!!! They use different words to hide what is really in it. I do not blame my stylist, she was misinformed by this company saying no Formaldehyde. I am 46 years old and this has effected me greatly.

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)	Yes

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)	KeratinComplex
	Name of the company that makes (or compounds) the product	https://www.ker atincomplex.com /
	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?	No
	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	Other	If Other	hair

Date the person first started taking or using the product	18-Jan-2019
Date the person stopped taking or using the product	18-Jan-2019
Give best estimate of duration	
Is therapy still on-going?	Yes

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

Hair smoothing

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)	46 Year(s)
Date of Birth	
Weight	50.4 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)

C5/ C6 discectomy and fusion April 2011. Thoracic Outlet syndrome. Now asthma, rashes and breathing issues since using Keratin Complex

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

Cats, dogs, mold, grass, trees, Allergy test taken- Feb 19, 2019

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

Past smoker, quit 5 1/2 years ago. Chest Xray- taken April 2011 for surgery and was clear.

List all current prescription medications and medical devices being used.

Symbacort, Albuteral

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

Allegra D

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	12-Apr-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):	No	

(b) (6)

...ROCESSED, GRAY, PLATINU... ...BLONDE, HIGHLIGHTS, OR CHEMICALLY TREATE...

...mes from root to end.

...ESISTANT: Pass the iron over each section 10 – 12 ...

...not use traditional shampoo or get the hair wet f... at least 72 hours after treatment. The ...

...into the hair during this 72-hour period. If the hai... gets wet, instruct the client to blow-...

...a flat iron on low heat if necessary. The client sho... wear their hair down and should...

...or glasses to hold or pull the hair back during th... period. After 72 hours, the hair may ...

...with Keratin Complex Keratin Care, Keratin Color C...e or Blondeshell® Shampoo and Co...

...eyes. If contact occurs, flush eyes with water. In the event of further irritation, consult ...

...a cool, dry place. Best used within two years afte... the lot number found on the bottom of ...

...Easy, Hydrolyzed Keratin, Timonacic, Cyclome...thicone, Dimethicone, Glyceryl Caprate, ...
...Gum, Caprylyl Methicone, Glycol Distearate, Cyamopsis Tetragonoloba Gum, ...
...Copolymer, Octanal, Amyl Acetate, Diethyl Phthalate, Hydroquinone, Iron Oxide ...

...Compliant. Product is safe if used as directed. If not used as directed, this ...
...and/or sensitization of the skin and/or respiratory system; eye and/or throat ...
...or carcinoma per IARC. Physical and health hazard information is readily ...
...OSS or by contacting us at info@keratincomplex.com or ...
...ASS).

...
...Boca Raton, FL 33487
...www.KeratinComplex.com

...11111CA102

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	24-May-2019	CTU Received Date	24-May-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)			

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)

Had a Brazilian blowout at my salon. Nobody mentioned any potential side effects, but day of treatment, they put me in a room with window open due to " fumes." A week later, I have blisters on my neck and forehead, and raised hives with intense itching on my scalp. Washing my hair is painful.

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)	Brazilian blowout
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

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)	60 Year(s)
Date of Birth	
Weight	67.5 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)