

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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> Had problems after switching from one product maker to another maker	
Did any of the following happen? (Check all that apply)	<input checked="" type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input checked="" type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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 Leukemia.	
---	--

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 :	<input type="checkbox"/>

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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)		

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> White <input type="checkbox"/> 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 :	<input checked="" type="checkbox"/>	

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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(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)	<input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input checked="" type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM	
Check all that apply	<input checked="" type="checkbox"/> Adverse Event <input type="checkbox"/> Product Use Error <input type="checkbox"/> Product Problem (e.g., defects/malfunctions) <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine
Serious	No
Outcome Attributed to Adverse Event (Check all that apply)	<input type="checkbox"/> Death <input type="checkbox"/> Life Threatening <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> Disability/Permanent Damage <input type="checkbox"/> Congenital Anomaly/Birth Defect <input type="checkbox"/> 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	<input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> 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	<input checked="" type="checkbox"/> Manufacturer/Compounder <input checked="" type="checkbox"/> User Facility <input checked="" type="checkbox"/> 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-039058 | CTU Triage Date: 28-10-2019 | Total Page

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

Mfr Report # US-JNJ-OC-20180719747

UF/Importer Report #

FDA Use Only

MEDWATCH
FORM FDA 3500A (10/15)

Page 1 of 4

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 <input checked="" type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) 69 <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 08 Feb 1925) 09-Sep-1959	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight <input type="checkbox"/> lb <input type="checkbox"/> kg
---	--	---	---

5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino	5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander
---	--

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)
2. Outcome Attributed to Adverse Event (Check all that apply) <input type="checkbox"/> Death Include date (dd-mmm-yyyy): <input type="checkbox"/> Life-threatening <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Congenital Anomaly/Birth Defects <input checked="" type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> 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 OGX EVER Continued	#1 - NDC # or Unique ID
#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

3. Dose	Frequency	Route Used Topical
#1		
#2		
4. Therapy Dates (If unknown give duration) from/ to (or best estimate) (dd-mmm-yyyy) #1 26-Feb-2017 -		9. Event Abated After Use Stopped or Dose Reduced? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
5. Diagnosis for Use (Indication) #1 UNKNOWN INDICATION		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
#2		10. Event Reappeared After Reintroduction? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
6. Is the Product Compounded? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> No		7. Is the Product Over-the-Counter? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> 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 Email Address ngami@its.jnj.com Compounding Outsourcing Facility 503B? <input type="checkbox"/> Yes	2. Phone Number 732-754-2672
3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input checked="" type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other	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) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up # 5	8. Adverse Event Term(s) 1) CHEMICAL POISONING (Chemical poisoning (10008428), Chemical Continued

E. INITIAL REPORTER

1. Name and Address 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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	3. Occupation Patient	4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk
---	--	--	--------------------------	--

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.

Date of This Report : 25-Oct-2019

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 bronzing 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-2019-125387 | Department: CFSAN | RCT No.: RCT-639058 | CTU Triage Date: 28-10-2019 | Total Page
 s: 4 Continuation Sheet for FDA-3500A Form Page 3 of 4 Mfr. Report #: 20180719747

Date of This Report : 25-Oct-2019

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 130Z
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

CTU No.: FDA-CDER-CTU-2019-125387 | Department: CFSAN | RCT No.: RCT-639058 | CTU Triage Date: 28-10-2019 | Total Page
Continuation Sheet for FDA-3500A Form Page 4 of 4 Mfr. Report #: 20180719747

Date of This Report : 25-Oct-2019

: 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

JNJ Consumer US Cosmetic

U.S. Department of Health and Human Services
Food and Drug AdministrationFor use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

FDA Facsimile Approval: 8/13/2007

File report #	US-JNJFOC-20180719747
UF/importer report #	
FDA use only	

MEDWATCH

3500A Facsimile

Page 1 of 3

A. PATIENT INFORMATION			
1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: Unknown Date of Birth: ??/??/????	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male UNK	4. Weight UNK lbs or UNK kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input checked="" type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input type="checkbox"/> Hospitalization - Initial or prolonged <input checked="" type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> 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 130Z (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			

C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & mfr/labeler)			
#1 OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z (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)		5. Event Abated After Use Stopped or Dose Reduced?	
#1 PRODUCT USED FOR UNKNOWN INDICATION		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK	
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK	
6. Lot #		7. Exp. Date	
#1 unknown		#1 ??/??/????	
#2		#2	
8. NDC# or Unique ID			
9. Event Reappeared After Reintroduction?			
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK			
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK			
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 #		5. Operator of Device	
Lot #		<input type="checkbox"/> Health Professional	
Catalog #		<input type="checkbox"/> Lay User/Patient	
Serial #		<input type="checkbox"/> Other	
Expiration Date (mm/dd/yyyy)			
Other #			
6. If Implanted, Give Date (mm/dd/yyyy)		7. If Explanted, Give Date (mm/dd/yyyy)	
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor			
10. Device Available for Evaluation? (Do not send to FDA)			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Unknown	
4. Initial Reporter Also Sent Report to FDA			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unk			

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

JNJ Consumer US Cosmetic

MEDWATCH

3500A Facsimile (Continued)

Page 2 of 3

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 <input type="checkbox"/> User Facility <input type="checkbox"/> 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 <input type="checkbox"/> Initial <input type="checkbox"/> 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? <input type="checkbox"/> Yes _____ (mm/dd/yyyy) <input type="checkbox"/> No		12. Location Where Event Occurred <input type="checkbox"/> Hospital <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Home <input type="checkbox"/> Nursing Home <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Other: _____ (Specify)	
13. Report Sent to Manufacturer? <input type="checkbox"/> Yes _____ (mm/dd/yyyy) <input type="checkbox"/> No			
14. Manufacturer Name/Address			

H. DEVICE MANUFACTURERS ONLY

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

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	
4. Date Received by Manufacturer (mm/dd/yyyy) 07/15/2018		3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input checked="" type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other: _____	
6. If IND, Give Protocol #		5. (A) NDA # IND # STN # PMA/ 510(K) #	
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> Initial <input type="checkbox"/> 15-day <input type="checkbox"/> Follow-up # _____		Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
9. Manufacturer Report Number US- JNJFOC-20180719747		8. Adverse Event Term(s) 1) CHEMICAL POISONING (Cont.)	

The public reporting burden for this collection of information has been estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

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

Continuation Sheet for FDA-3500A Form

Page 3 of 3

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman

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

JNJ Consumer US Cosmetic

U.S. Department of Health and Human Services
Food and Drug AdministrationFor use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

FDA Facsimile Approval: 01/30/2007

MEDWATCH

3500A Facsimile

CFSAN

Page 1 of 4

Mfr report # US-JNJFOC-20180719747 IIF file name of 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 <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight UNK bs or UNK kgs
---	--	---	--------------------------------------

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or <input checked="" type="checkbox"/> Product Problem (e.g., defects/malfunctions)	
2. Outcomes Attributed to Adverse Event (Check all that apply)	
<input type="checkbox"/> Death (immediacy)	<input type="checkbox"/> Disability or Permanent Damage
<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Congenital Anomaly/Birth Defect
<input type="checkbox"/> Hospitalization - initial or prolonged	<input checked="" type="checkbox"/> Other Serious (Important Medical Events)
<input type="checkbox"/> Required intervention to Prevent Permanent Impairment/Damage(Devices)	
3. Date of Event (immediacy) ??/??/????	4. Date of This Report (immediacy) 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: 000211323.

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 1302 (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

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr labeler)	
#1 OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 1302 (OGX EVER STRAIGHTENING) Shampoo	
#2	
2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) (immediacy)
#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 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
6. Lot #	7. Exp. Date
#1 unknown	#1 ??/??/????
#2	#2
8. Event Reappeared After Reintroduction?	
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK	
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 (immediacy)	<input type="checkbox"/> Health Professional
Serial #	Other #	<input type="checkbox"/> Lay User/Patient
		<input type="checkbox"/> Other
6. If Implanted, Give Date (immediacy)		7. If Expired, Give Date (immediacy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?		
<input type="checkbox"/> Yes <input type="checkbox"/> No		
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor		
10. Device Available for Evaluation? (Do not send to FDA)		
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on: (immediacy)		
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
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unk

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

JNJ Consumer US Cosmetic

MEDWATCH

3500A Facsimile (Continued)

Page 2 of 4



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

1. Check One <input type="checkbox"/> User Facility <input type="checkbox"/> 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 <input type="checkbox"/> Initial <input type="checkbox"/> 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? <input type="checkbox"/> Yes (mm/dd/yyyy) <input type="checkbox"/> No		12. Location Where Event Occurred <input type="checkbox"/> Hospital <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Home <input type="checkbox"/> Nursing Home <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Other: (Specify)	
13. Report Sent to Manufacturer? <input type="checkbox"/> Yes (mm/dd/yyyy) <input type="checkbox"/> No		14. Manufacturer Name/Address	

H. DEVICE MANUFACTURERS ONLY

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

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	
4. Date Received by Manufacturer (mm/dd/yyyy) 08/30/2018		3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input checked="" type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other:	
6. If IND, Give Protocol #		5. (A) NDA # IND # STN # PMA/510(K) # Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up #		8. Adverse Event Term(s) 1) CHEMICAL POISONING	
9. Manufacturer Report Number US- JNJFOC-20180719747		(Cont.)	

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman

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

Continuation Sheet for FDA-3500A Form

Page 3 of 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 bronzing cancer going through whole body.

Action taken with OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (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 130Z (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

JNJ Consumer US Cosmetic

199 Grandview Road

Skillman

Mfr. report#: US-JNJFOC-20180719747

Date of this report: 09/20/2018

Continuation Sheet for FDA-3500A Form

Page 4 of 4

20180828488, 20180901076, 20180903071 and 20180724202.

Senders Comments/Medical Assessment:

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

Lab Result:

Test Name

BIOPSY

Test Date

??/??/????

Test Result

unknown

Normal High

Normal Low

G8. Adverse Event Term (Cont...)

2) PRODUCT FORMULATION ISSUE

JNJ Consumer US Cosmetic

FDA Form/Rev. 01/30/2007

U.S. Department of Health and Human Services
Food and Drug AdministrationFor use by user-facilities,
distributors and manufacturers for
MANDATORY reporting**MEDWATCH**

3500A Facsimile

Page 1 of 4

MR report #	US-JNJFOC-20180719747
UPP/monitor report #	
FDA use only	

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)	2. Age at Time of Event: or 68 Years Date of Birth: ??/??/????	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight lbs or kgs UNK
In confidence			

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or <input checked="" type="checkbox"/> Product Problem (e.g., defects/malfunctions)	
2. Outcomes Attributed to Adverse Event (Check all that apply)	
<input type="checkbox"/> Death: (mm/dd/yyyy)	<input type="checkbox"/> Disability or Permanent Damage
<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Congenital Anomaly/Birth Defect
<input type="checkbox"/> Hospitalization - initial or prolonged	<input checked="" type="checkbox"/> Other Serious (Important Medical Events)
<input type="checkbox"/> 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 130Z (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

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)	
#1 OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z (OGX EVER STRAIGHTENING) Shampoo	
#2	
2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration from onset (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 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply Apply
6. Lot #	7. Exp. Date
#1 unknown	#1 ??/??/????
#2	#2
8. Event Reappeared After Reintroduction?	
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK	
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply 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 #	5. Operator of Device
Catalog #	<input type="checkbox"/> Health Professional
Serial #	<input type="checkbox"/> Lay User/Patient
Expiration Date (mm/dd/yyyy)	<input type="checkbox"/> Other
Other #	
6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor	
10. Device Available for Evaluation? (Do not send to FDA)	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	3. Occupation Unknown
4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unk	

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

JNJ Consumer US Cosmetic

MEDWATCH

3500A Facsimile (Continued)

Page 2 of 4

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 <input type="checkbox"/> User Facility <input type="checkbox"/> 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 <input type="checkbox"/> Initial <input type="checkbox"/> 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? <input type="checkbox"/> Yes (mm/dd/yyyy) <input type="checkbox"/> No	12. Location Where Event Occurred <input type="checkbox"/> Hospital <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Home <input type="checkbox"/> Nursing Home <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Other: (Specify)		
13. Report Sent to Manufacturer? <input type="checkbox"/> Yes (mm/dd/yyyy) <input type="checkbox"/> 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	
4. Date Received by Manufacturer (mm/dd/yyyy) 01/13/2019		3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input checked="" type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other:	
6. If IND, Give Protocol #	5. (A) NDA # IND # STN # PMA/ 510(K) # Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes		
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up # 2			
9. Manufacturer Report Number US-JNJFOC-20180719747		8. Adverse Event Term(s) 1) CHEMICAL POISONING (Cont.)	

H. DEVICE MANUFACTURERS ONLY

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

The public reporting burden for this collection of information has been estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

JNJ Consumer US Cosmetic
199 Grandview Road
Skillman

Continuation Sheet for FDA-3500A Form

Page 3 of 4

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

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 bronzing 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

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

Continuation Sheet for FDA-3500A Form

Page 4 of 4

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 Date	Test Result	Normal High	Normal Low
Test Name				
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

1

JNJ Consumer US Cosmetic

U.S. Department of Health and Human Services
Food and Drug AdministrationFor use by user-facilities,
distributors and manufacturers for
MANDATORY reporting**MEDWATCH**

3500A Facsimile

Page 1 of 4

FDA Facsimile Approval: 01/08/2007

Mr report #	US-JNJFOC-20180719747
UF/Reporter 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 <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight lbs or kgs UNK
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input checked="" type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death: (mm/dd/yyyy) <input type="checkbox"/> Life-threatening <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage(Devices) <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" type="checkbox"/> Other Serious (Important Medical Events)			
3. Date of Event (mm/dd/yyyy) ??/??/????		4. Date of This Report (mm/dd/yyyy) 06/12/2019	
5. Describe Event or Problem			
<p>This spontaneous report received from a patient of unknown age and gender reporting on self from United States via social media: 000311323.</p> <p>The patient's weight, height and medical history were unknown.</p> <p>On an unspecified date, the patient started using OCX EVER STRAIGHTENING BRAZIL KERATIN THERAPY CONDITIONER 130Z (EVER STRAIGHT BRAZILIAN KERATIN THERAPY CONDITIONER 386) (topical, dose and frequency unspecified) for unknown indication. Concomitant medications</p> <p style="text-align: right;">(Cont.)</p>			
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			

C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & manufacturer)			
#1 OCX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z (OCX 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 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK	
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot #	7. Exp. Date		8. Event Reappeared After Reintroduction?
#1 unknown	#1 ??/??/????		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK
#2	#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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)	<input type="checkbox"/> Health Professional	
Serial #	Other #	<input type="checkbox"/> Lay User/Patient	
		<input type="checkbox"/> Other	
6. If Implanted, Give Date (mm/dd/yyyy)		7. If Expired, Give Date (mm/dd/yyyy)	
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? <input type="checkbox"/> Yes <input type="checkbox"/> No			
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor			
10. Device Available for Evaluation? (Do not send to FDA) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	3. Occupation Unknown	4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unk	

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

JNJ Consumer US Cosmetic

MEDWATCH

3500A Facsimile (Continued)

Page 2 of 4

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 <input type="checkbox"/> User Facility <input type="checkbox"/> 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 <input type="checkbox"/> Initial <input type="checkbox"/> 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? <input type="checkbox"/> Yes _____ (mm/dd/yyyy) <input type="checkbox"/> No		12. Location Where Event Occurred <input type="checkbox"/> Hospital <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Home <input type="checkbox"/> Nursing Home <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Other: _____ (Specify)	
13. Report Sent to Manufacturer? <input type="checkbox"/> Yes _____ (mm/dd/yyyy) <input type="checkbox"/> 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	
4. Date Received by Manufacturer (mm/dd/yyyy) 06/01/2019		3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input checked="" type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other: _____	
6. If IND, Give Protocol #		5. (A) NDA # _____ IND # _____ STN # _____ PMA/ 510(K) # _____ Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up # _____ 3			
9. Manufacturer Report Number US-JNJFOC-20180719747		8. Adverse Event Term(s) 1) CHEMICAL POISONING (Cont.)	

H. DEVICE MANUFACTURERS ONLY

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

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

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

Mfr. report#: US-JNJFOC-20180719747

Date of this report: 06/12/2019

Continuation Sheet for FDA-3500A Form

Page 3 of 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 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

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

Mfr. report#: US-JNJFOC-20180719747

Date of this report: 06/12/2019

Continuation Sheet for FDA-3500A Form

Page 4 of 4

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

Mfr Report # IIS-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 <input checked="" type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) 68 <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 09 Feb 1925) (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight <input type="checkbox"/> lb. <input type="checkbox"/> kg
---	--	---	--

5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino	5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander
---	--

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)
2. Outcome Attributed to Adverse Event (Check all that apply) <input type="checkbox"/> Death Include date (dd-mmm-yyyy): <input type="checkbox"/> Life-threatening <input type="checkbox"/> Hospitalization - Initial or prolonged <input checked="" type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> 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; 600311323.
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

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 -	9. Event Abated After Use Stopped or Dose Reduced? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
--	---

5. Diagnosis for Use (Indication) #1 UNKNOWN INDICATION	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
--	---

#2 UNKNOWN INDICATION	10. Event Reappeared After Reintroduction? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
-----------------------	---

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

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

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices) Name UNJ Consumer US Cosmetic Address OCMS 199 Grandview Road Skillman, NJ Email Address ngami@its.jnj.com	2. Phone Number 732 754 2672
3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input checked="" type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other	

4. Date Received by Manufacturer (dd-mmm-yyyy) 05-Jan-2020	5. NDA # ANDA # IND # BLA # PMA # S10(k) #
---	---

6. If IND, Give Protocol #	7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up # 7
Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC <input type="checkbox"/> 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 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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	3. Occupation Patient	4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk
---	--	--	--------------------------	--

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.

CTU No.: FDA-CDER-CTU-2020-7931 | Department: CFSAN | RCT No.: RCT-768891 | CTU Triage Date: 22-01-2020 | Total Pages: 4
Continuation Sheet for FDA-3500A Form Page 2 of 4 Mfr. Report #: 20180719747

Date of This Report : 21-Jan-2020

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 bronzing 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
 Continuation Sheet for FDA-3500A Form Page 3 of 4 Mfr. Report #: 20180719747

Date of This Report : 21-Jan-2020

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
 Continuation Sheet for FDA-3500A Form Page 4 of 4 Mfr. Report #: 20180719747

Date of This Report : 21-Jan-2020

(Biopsy)

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

Seq No.	: 1
C.1 Suspect Product	: OGX EVER STRAIGHTENING BRAZIL KERATIN THERAPY COND 130Z
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-786282 | CTU Triage Date: 02-03-2020 | Total Pages

Form Approved: OMB No. 0910-0261, Expires: 9/30/2018

See PRA statement on reverse.

U.S. Department of Health and Human Services
Food and Drug AdministrationFor 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 <input checked="" type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 08 Feb 1925) (b) (6)	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight <input type="checkbox"/> lb <input type="checkbox"/> kg
---	--	---	---

5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino	5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander
---	--

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)
2. Outcome Attributed to Adverse Event (Check all that apply) <input type="checkbox"/> Death Include date (dd-mmm-yyyy): <input type="checkbox"/> Life-threatening <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Congenital Anomaly/Birth Defects <input checked="" type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> 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 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

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 -		9. Event Abated After Use Stopped or Dose Reduced? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
5. Diagnosis for Use (Indication) #1 UNKNOWN INDICATION		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
#2 UNKNOWN INDICATION		10. Event Reappeared After Reintroduction? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
6. Is the Product Compounded? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> No		7. Is the Product Over-the-Counter? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> 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 Email Address ngami@its.jnj.com Compounding Outsourcing Facility 503B? <input type="checkbox"/> Yes	2. Phone Number 732-754-2672
3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input checked="" type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other	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) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up #_5	8. Adverse Event Term(s) 1) CHEMICAL POISONING (Chemical poisoning (10008428), Chemical Continued

E. INITIAL REPORTER

1. Name and Address 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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	3. Occupation Patient	4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk
---	--	--	--------------------------	--

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.

Date of This Report : 28-Feb-2020

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 bronzing 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-2020-24824 | Department: CFSAN | RCT No.: RCT-786282 | CTU Triage Date: 02-03-2020 | Total Pages
Continuation Sheet for FDA-3500A Form Page 3 of 4 Mfr. Report #: 20180719747

Date of This Report : 28-Feb-2020

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 STRIGHTNER 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.

CTU No.: FDA-CDER-CTU-2020-24824 | Department: CFSAN | RCT No.: RCT-786282 | CTU Triage Date: 02-03-2020 | Total Pages
 Continuation Sheet for FDA-3500A Form Page 4 of 4 Mfr. Report #: 20180719747

Date of This Report : 28-Feb-2020

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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input checked="" type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input checked="" type="checkbox"/> Asian <input type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)		

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> 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)	
<p>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 symptoms. sensation during styling or when it got close to my eyes. Following the treatment I had trouble breathing and often times 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.</p>	

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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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 or allergies

List all current prescription medications and medical devices being used.

amoxicillin - to treat 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)		

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> 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)	
<p>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 persistent and could not be completely removed even after 6 shampoos. I do not have the container for this product since it is owned by the salon.</p>	

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

Section B - About the Products	
--------------------------------	--

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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input checked="" type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)		

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> Other serious/important medical incident	

Tell us what happened and how it happened (Include as many details as possible)	
<p>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.</p>	

List any relevant tests or laboratory data if you know them (Include dates)	
<p>I researched the chemicals in the product and also had a chemist analyze them and found out that galoxyloyl carbocysteine is an aldehyde.</p>	

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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input checked="" type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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)	Brazilian 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)			

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> Other serious/important medical incident
Other serious/important medical incident	

Tell us what happened and how it happened (Include as many details as possible)	
<p>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.</p>	

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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input checked="" type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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 at 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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

(b) (6)

Last Name

(b) (6)

Primary Phone

(b) (6)

Mail/Zip Code

00000

Country

United States

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

I am the affected person

Suspect Product

Product Type

Cosmetic

Product Name

OGX BRAZILIAN THERAPY STRAIGHTENING CONDITIONER

Affected Individual

Gender

Female

Age at the time of event

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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)		(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input checked="" type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> Other serious/important medical incident

Tell us what happened and how it happened (Include as many details as possible)	
<p>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. Thighs 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.</p>	

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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> White <input type="checkbox"/> 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm <input checked="" type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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)

<p>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.</p>
--

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.keratincomplex.com /	
Product Type(check all that apply)	<input type="checkbox"/> Over-the-Counter <input type="checkbox"/> Compounded by a Pharmacy or an Outsourcing Facility <input type="checkbox"/> Generic <input type="checkbox"/> 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> 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.

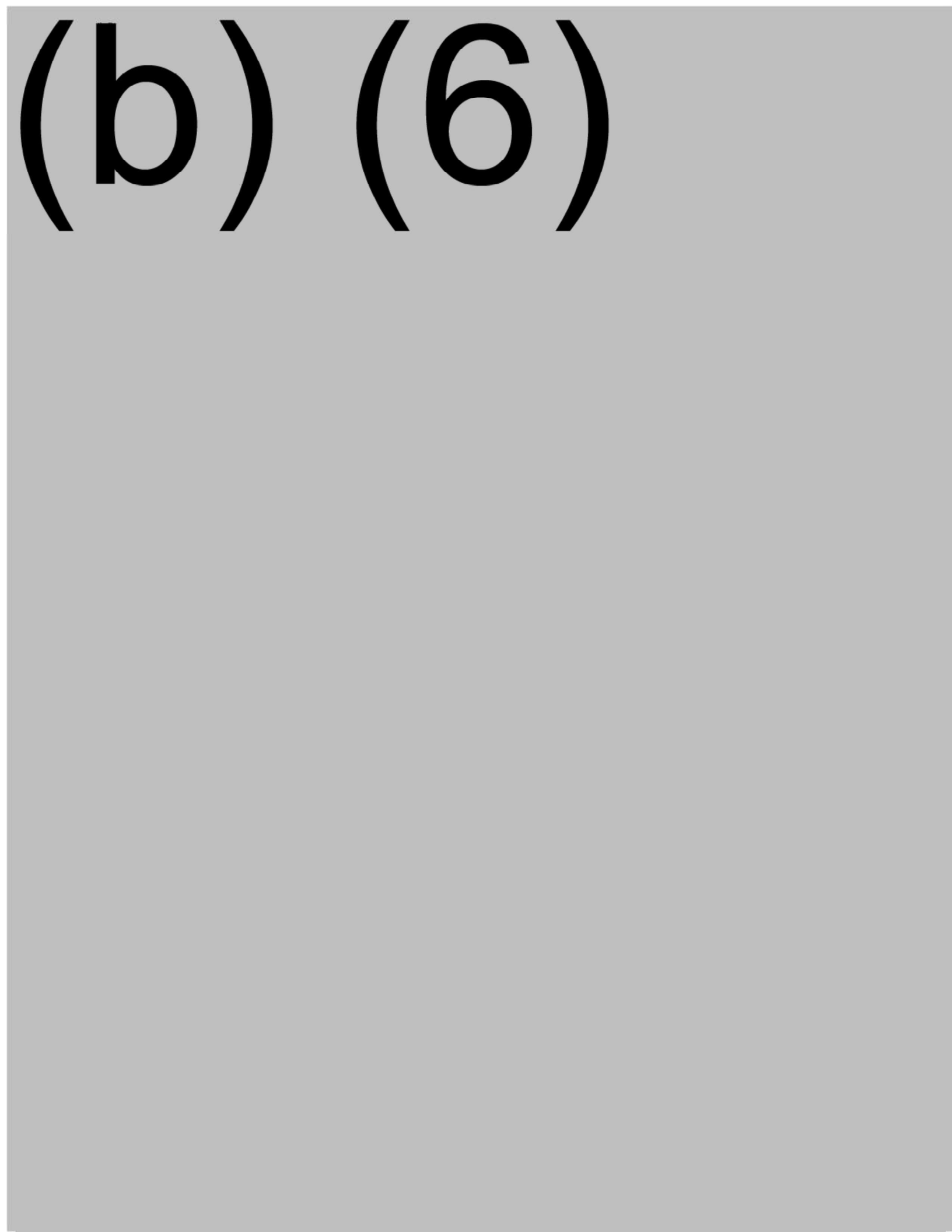
Allegra D

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)

...PROCESSED, GRAY, PLATINUM, OR CHEMICALLY TREATED HAIR.
...BLEND, HIGHLIGHTS, OR CHEMICALLY TREATED HAIR.
...Pass the iron over each section 10 - 12 times from root to end.
...at least 72 hours after treatment. The client should not use traditional shampoo or get the hair wet for at least 72 hours after treatment. The client should wear their hair down and should not use a flat iron on low heat if necessary. If the hair gets wet, instruct the client to blow-dry the hair. After 72 hours, the hair may be washed with Keratin Complex Keratin Care, Keratin Color Care or Blondeshell® Shampoo and Conditioner. If contact occurs, flush eyes with water. In the event of further irritation, consult your physician. Best used within two years after the lot number found on the bottom of the bottle in a cool, dry place.

Ingredients: Water, Hydrolyzed Keratin, Timonacic, Cyclomethicone, Dimethicone, Glyceryl Caprylate, Caprylyl Methicone, Glycol Distearate, Cyamopsis Tetragonoloba Gum, Octanal, Amyl Acetate, Diethyl Phthalate, Hydroquinone, Iron Oxides, and other ingredients.

Product is safe if used as directed. If not used as directed, this product may cause irritation of the skin and/or respiratory system; eye and/or throat irritation; or by contacting us at info@keratincomplex.com or 1-800-333-1550. Physical and health hazard information is readily available.

Lot: 1111CA102
www.keratincomplex.com



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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)			

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm <input checked="" type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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)	<input type="checkbox"/> Over-the-Counter <input type="checkbox"/> Compounded by a Pharmacy or an Outsourcing Facility <input type="checkbox"/> Generic <input type="checkbox"/> Biosimilar	
	Strength	<div style="display: flex; justify-content: space-between;"> If Other </div>	
	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	<div style="display: flex; justify-content: space-between;"> If Other </div>	
	Frequency	<div style="display: flex; justify-content: space-between;"> If Other </div>	
	How was it taken or used	<div style="display: flex; justify-content: space-between;"> If Other </div>	
	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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> Black or African American

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