



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Thomas Cluderay
Environmental Working Group
1436 U ST, NW
Suite 100
Washington, DC 20009

FEB 11 2011

Food and Drug Administration
Rockville MD 20857

F11-394

Dear Mr. Cluderay:

In response to your request of January 10, 2011 for adverse event reports involving Brazilian Blowout products or any other hair straightening, hair straightener, or keratin hair product.

XX Enclosed are the records you requested.

 We have searched our files and find no responsive information.

 Your request is also being referred to one of our component offices.

 Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination with respect to these records and would like FDA to reconsider any particular deletion, please let us know in writing at the following address: Food and Drug Administration, Division of Freedom of Information, 12420 Parklawn Drive, Room 1050 Rockville, MD 20850 within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed with respect to these records. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.

The following charges for this request to date may be included in a monthly invoice:

Reproduction\$ 0 Search\$ 0 Review\$ 0 Other\$ 0 Total:\$ 0

THE ABOVE TOTAL MAY NOT REFLECT THE FINAL CHARGES FOR THIS REQUEST.
PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE.

Sincerely yours,

FOI OFFICER
Executive Operations Staff
Center for Food Safety
and Applied Nutrition

Enclosure

CAERS Reports Allegedly Related to Brazilian Blowout - 1/14/2011

Search Terms: Brazilian Blowout, Hair Straightener, Keratin

CAERS is a post-market surveillance system that collects voluntary adverse event reports and product complaints that are allegedly related to CFSAN regulated products. Adverse event reports submitted to FDA are voluntary and vary in the quality and reliability of information provided. In some reports, information in the reports cannot be verified for accuracy of the symptom(s), product(s), or ingredient(s). Furthermore, in many reports, individuals may have used other products, and many products contain multiple ingredients which further complicates the evaluation of adverse event reports.

There is no certainty that a reported adverse event can be attributed to a particular product or ingredient. The number of adverse event reports in CAERS received by FDA and the adverse event report itself about a particular product only reflects information AS REPORTED and does not represent any conclusion by FDA regarding a causal relationship or association with the product or ingredient. Due to the continuous inclusion of new or updated information into the CAERS system, reports released from CAERS containing adverse event data may change over time.





RA_Rep ort #	RA_Initia l Report Date	SO_FDA Received Date	PRI_Reported Brand/Product Name	PI_One Row Ingredients	PI_Ingrdie nt Category	PRI_Produc t Comments	PRM_Firm Name	PRM_Firm Type	SO_Report Format	PRM_Firm Address Type	AEC_Event As Reported
											<p>I PURCHASED SOFTSHEEN/CARSON PROFESSIONAL ULTRA PRECISE NO-LYE CONDITIONING RELAXER ON JANUARY 27, 2009. THEY ARE LOCATED AT SOFT SHEEN/CARSON, INC., DIST., NEW YORK, N.Y. 10017. I APPLIED THE RELAXER AS INSTRUCTED ON FEBRUARY 13, 2009. UPON RINSING RELAXER OUT, MY HAIR FELL OUT, AND THERE WERE BALD SPOTS IN THE MIDDLE OF MY HEAD. I EXPERIENCE EXTREME ITCHING, SCALP IRRITATION, AND HAD SOME SCARRING. I WENT DIRECTLY TO STORE FROM WHICH I PURCHASED PRODUCT INFORMED OWNER MY DAMAGED HAIR, OWNER STATED BECAUSE I DID NOT HAVE RECEIPT IN HAND HE WOULD NOT DO ANYTHING, I SHOWED OWNER BOX WHICH STORE STAMP ON IT HE BECAME RUDE AND BELLIGERENT. I THEN WENT TO DOCTOR. THE PHYSICIAN RECOMMENDED I CONSULT A DERMATOLOGIST. DIAGNOSED WITH ALOPECIA AND DERMATITIS. MY HAIR CONTINUES TO FALL OUT DAILY. I HAVE BEEN TO A COSMETOLOGIST WHO SPECIALIZES IN DAMAGED HAIR, BUT TO NO AVAIL. SINCE THIS HAPPENED TO ME, I AM EXTREMELY CONCERNED AFTER READING ARTICLE AFTER ARTICLE ON SIDE EFFECTS.</p> <p>OF HAIR RELAXERS THAT ARE MARKETED TO AFRICAN AMERICAN FEMALES FOR HOME USE. THE FDA HAS NOT HELD THESE COMPANIES LIABLE TO THE CONSTANT SIDE EFFECTS OF HAIR RELAXERS. THEY MARKET THESE PRODUCTS AS NO-LYE AND THEY DO NOT HAVE LYE IN THEM. COMPANIES ARE ALLOWED TO NOT POST EXPIRATION DATES, WHICH ARE IMPERATIVE TO HAVE IF THE CHEMICAL COMPOSITION CHANGES OVER TIME THEY CAN CAUSE EXTREME SIDE EFFECTS. THERE IS NO EXPIRATION DATE ON THIS PRODUCT ONLY A CODE. I CONTACTED THE MANUFACTURER TO IDENTIFY THE CODE. THE PRODUCT IS A LITTLE BEYOND 3 YEARS OLD. THE COMPANY WEB-SITE STATES THAT STALE PRODUCTS COULD CAUSE</p>

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✓ 111264	03/17/09	03/19/09	SOFTSHEEN/CARSON/ULTRA PRECISE NO- LYE RELAXER SUPREME FORMULA	UNKNOWN	Ingredient From Label	NA	SOFTSHEEN- CARSON	Corporate Headquarters	MW 3500	From Other Sources	<p>SEVERE HAIR-LOSS AND BREAKAGE IF THE PRODUCT IS BEYOND THE SHELF-LIFE. THERE WAS NOT ANY DATE ON THE PRODUCT TO VERIFY IF IT WAS OLD. HOW DARE THE FDA BE SO RECKLESS AS TO ALLOW A COSMETIC MANUFACTURER TO SET IT OWN STANDARDS AND NOT PROVIDE PROPER OVERSIGHT TO ENSURE SAFETY TO THE CONSUMERS. THIS IS A TRUE TRAVESTY. THERE SHOULD BE MANDATORY GUIDELINES INSTEAD OF VOLUNTARY SHELF-LIFE GUIDELINES. I HAVE READ THAT EXPIRATION DATES ARE ONLY ?RULES OF THUMB ? HOW MANY WOMEN MUST SUFFER FROM THIS LACK OF OVERSIGHT AND IMPROPER INTEGRITY TO SUBSTANTIATE PRODUCT SAFETY? RELEVANT TESTS. AN ARTICLE IN OCTOBER 2005 BY NKECHI NNORUKA IN THE INTERNATIONAL JOURNAL OF DERMATOLOGY, VOLUME 44, PP 13-17 ?HAIR LOSS IS THERE A RELATIONSHIP WITH HAIR CARE PRACTICES IN NIGERIA?? STATES A TOTAL OF 39 WOMEN HAD COMPLAINTS OF EITHER HAIR LOSS, ITCHY SCALP, AND</p> <p>BREAKAGE. ALL THE WOMEN HAD THEIR HAIR AT SAME TIME. AN ARTICLE IN OCTOBER 2007 BY BEATRICE A. ETMESI, MD IN THE INTERNATIONAL JOURNAL OF DERMATOLOGY, VOLUME 46 ISSUE S1, PP 23-25 ?IMPACT OF HAIR RELAXERS IN WOMEN IN NAKURU, KENYA ? STATES 240 WOMEN WERE RECRUITED GIVEN RELAXERS. 134 WOMEN HAD PROBLEMS WITH RELAXERS AT LEAST ONCE. PROBLEMS INCURRED WERE HAIR LOSS, BURNS TO SCALP, AND COLOR CHANGE. AN ARTICLE IN THE BRITISH JOURNAL OF DERMATOLOGY VOLUME 157 -1- JULY 2007 PP. 106-110 ?HAIRDRESSING IS ASSOCIATED WITH SCALP DISEASE IN AFRICAN SCHOOL CHILDREN? A CROSS SECTIONAL STUDY OF 1042 CHILDREN WAS DONE. 78.4% OF THE GIRLS HAD CHEMICALLY RELAXED HAIR. 98 OF 1042 -TA- TRACTION ALOPECIA WAS SIGNIFICANTLY MORE COMMON WITH RELAXED HAIR. AN ARTICLE BY DR. ALL SYEDIN SHOP TALK MAGAZINE, SHELF LIFE AND STORAGE OF SALON PRODUCTS ? STATES AS A PRODUCT AGES, THE ENVIRONMENT- I.E. TEMPERATURE, EXPOSURE TO AIR, ECT ?MAY CAUSE THE PRODUCT THAT IS BEYOND ITS SHELF LIFE WILL NOT</p> <p>PERFORM AS EFFECTIVELY AS IT DID INITIALLY. PRODUCT APPLICATION MAY BE IMPAIRED AND THE WAY IT REACTS TO HAIR IN A VERY WELL BE HINDERED. AT WORST, THE PRODUCT COULD CAUSE HARM TO A CLIENT ? OTHER RELEVANT HISTORY. I HAVE NO PREEXISTING MEDICAL CONDITIONS. 20 YEARS OF RELAXED HAIR ?RACE- AFRICAN AMERICAN</p>

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113679	05/18/09	05/18/09	BRAZILIAN BLOW-OUT	ALDEHYDE	Reported Ingredient	NA	UNKNOWN	Corporate Headquarters	FACTS	From Other Sources	CAERS REPORTS 113679, 113833 AND 113834 ARE REALTED REPORT 113679 IS FOR [REDACTED], REPORT 113833 IS FOR HAIRSTYLIST #1, REPORT 113834 IS FOR HAIRSTYLIST #2 THE COMPLAINANT, MS [REDACTED] STATED THE SALON WHERE SHE IS A HAIRSTYLIST USED BRAZILIAN BLOW-OUT, A HAIR- STRAIGHTENING PRODUCT, ON FRIDAY, MAY 15, 2009 THE PRODUCT HAD A STRONG CHOCOLATE SMELL WHICH SHE SAID IS AN INDICATOR OF HIGH ALDEHYDE LEVELS MS [REDACTED] STATED THE SMELL FROM THE PRODUCT CAUSED HER EYES TO BURN THE SMELL CAUSED TWO HAIRSTYLISTS TO HAVE BREATHING PROBLEMS AND ONE OF THEM HAD TO LEAVE WORK ONE MAN AT THE SALON GOT A HEADACHE AND ALSO HAD TO LEAVE NOBODY SOUGHT MEDICAL ATTENTION DUE TO THE PRODUCT MS [REDACTED] SAID A HIGH DEGREE OF HEAT IS USED IN THE PROCESS OF HAIR STRAIGHTENING WHICH SHE BELIEVES INCREASES THE ALDEHYDE COMPLAINT / INJURY REMARKS DIFFICULTY BREATHING, BURNING SENSATION IN EYES AND HEADACHE FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) DIFFICULTY BREATHING / NR / NR / NR / NR / BURNING SENSATION IN EYES AND HEADACHE ALSO OCCURRE
										Preferred	
									Letter/Fax/Ph one	From Other Sources	
										Preferred	
113833	05/18/09	05/18/09	BRAZILIAN BLOW-OUT	UNKNOWN, ALDEHYDE	Alleged Problem Ingredient not on label	NA	UNKNOWN	Manufacturer	FACTS	From Other Sources	CAERS REPORTS 113679, 113833 AND 113834 ARE REALTED REPORT 113679 IS FOR [REDACTED], REPORT 113833 IS FOR HAIRSTYLIST #1, REPORT 113834 IS FOR HAIRSTYLIST #2 THE COMPLAINANT, MS [REDACTED] STATED THE SALON WHERE SHE IS A HAIRSTYLIST USED BRAZILIAN BLOW-OUT, A HAIR- STRAIGHTENING PRODUCT, ON FRIDAY, MAY 15, 2009 THE PRODUCT HAD A STRONG CHOCOLATE SMELL WHICH SHE SAID IS AN INDICATOR OF HIGH ALDEHYDE LEVELS MS [REDACTED] STATED THE SMELL FROM THE PRODUCT CAUSED HER EYES TO BURN THE SMELL CAUSED TWO HAIRSTYLISTS TO HAVE BREATHING PROBLEMS AND ONE OF THEM HAD TO LEAVE WORK ONE MAN AT THE SALON GOT A HEADACHE AND ALSO HAD TO LEAVE NOBODY SOUGHT MEDICAL ATTENTION DUE TO THE PRODUCT MS [REDACTED] SAID A HIGH DEGREE OF HEAT IS USED IN THE PROCESS OF HAIR STRAIGHTENING WHICH SHE BELIEVES INCREASES THE ALDEHYDE COMPLAINT / INJURY REMARKS DIFFICULTY BREATHING, BURNING SENSATION IN EYES AND HEADACHE FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) DIFFICULTY BREATHING / NR / NR / NR / NR / BURNING SENSATION IN EYES AND HEADACHE ALSO OCCURRE
										Preferred	
					Ingredient From Label				Letter/Fax/Ph one	From Other Sources	
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113834	05/18/09	05/18/09	BRAZILIAN BLOW-OUT	UNKNOWN, ALDEHYDE	Alleged Problem Ingredient not on label	NA	UNKNOWN	Manufacturer	FACTS	From Other Sources	CAERS REPORTS 113679, 113833 AND 113834 ARE REALTED REPORT 113679 IS FOR [REDACTED], REPORT 113833 IS FOR HAIRSTYLIST #1; REPORT 113834 IS FOR HAIRSTYLIST #2 THE COMPLAINANT, MS [REDACTED] STATED THE SALON WHERE SHE IS A HAIRSTYLIST USED BRAZILIAN BLOW-OUT, A HAIR- STRAIGHTENING PRODUCT, ON FRIDAY, MAY 15, 2009 THE PRODUCT HAD A STRONG CHOCOLATE SMELL WHICH SHE SAID IS AN INDICATOR OF HIGH ALDEHYDE LEVELS MS [REDACTED] STATED THE SMELL FROM THE PRODUCT CAUSED HER EYES TO BURN THE SMELL CAUSED TWO HAIRSTYLISTS TO HAVE BREATHING PROBLEMS AND ONE OF THEM HAD TO LEAVE WORK ONE MAN AT THE SALON GOT A HEADACHE AND ALSO HAD TO LEAVE NOBODY SOUGHT MEDICAL ATTENTION DUE TO THE PRODUCT MS [REDACTED] SAID A HIGH DEGREE OF HEAT IS USED IN THE PROCESS OF HAIR STRAIGHTENING WHICH SHE BELIEVES INCREASES THE ALDEHYDE COMPLAINT / INJURY REMARKS DIFFICULTY BREATHING, BURNING SENSATION IN EYES AND HEADACHE FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) DIFFICULTY BREATHING / NR / NR / NR / NR / BURNING SENSATION IN EYES AND HEADACHE ALSO OCCURRE
					Ingredient From Label				Letter/Fax/Ph one	From Other Sources	
										Preferred	
120110	01/15/09	01/15/09	DR MIRACLE'S/FEE L IT FORMULA THERMALCEUTI CAL INTENSIVE NO-LYE RELAXER	UNKNOWN	Ingredient From Label	PURCHASE DATE 11/08	[REDACTED]	Manufacturer	FACTS	From AE Report	COMPLAINANT USED PRODUCT AND SUFFERED AN ADVERSE REACTION (COMPLETE HAIR LOSS OVER TIME) COMPLAINT/INJURY REMARKS USED A HAIR PRODUCT USED TO STRAIGHTEN OR RELAX (HAIR RELAXER) CURLY HAIR COMPLAINANT STATED THAT SHE USED THE PRODUCT ACCORDING TO THE DIRECTIONS COMPLAINANT EXPERIENCED BURNING OF THE SCALP AND SOME HAIR LOSS (HAIR BEGAN FALLING OUT IN CLUMPS) AT FIRST AND THEN AFTER A FEW MONTHS WAS BALD HER SCALP WAS SORE SINCE THEN HER HAIR APPEARS TO BE STARTING TO GROW BACK AND SCALP IS NOT AS SORE SPOKE WITH [REDACTED] @ PHONE 4[REDACTED] FOR THE INFORMATION REGARDING THE MANUFACTURER OF THE PRODUCT, AZIZI STATED THAT THERE WAS ONLY ONE MANUFACTURER, LOCATED IN [REDACTED] (SEE DATA ON PAGE 2 FOR MANUFACTURER INFORMATION) COSMETIC REMARKS THIS OCCURED IN NOVEMBER AND NO TREATMENT HAS BEEN SOUGHT OR PHYSICIAN VISITS HAVE BEEN MADE PER HER COMPLAINT FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) BALDING / 1 5 / MONTH(S) / NR / IMMEDIATE / NR
									Letter/Fax/Ph one		



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✓ 124344	03/11/10	03/12/10	BRAZILIAN KERATIN TREATMENT	UNKNOWN	Ingredient From Label	NA	UNKNOWN	Manufacturer	MW 3500	From AE Report	USING BRAZILIAN KERATIN TREATMENT -CONTAINS FORMALDEHYDE- PERSON EXPERIENCED HEADACHES, DIZZINESS, AND BLURRED VISION OTHER RELEVANT HISTORY AFRICAN AMERICAN AND HEALTHY
✓ 125176	03/26/10	03/26/10	BRAZILIAN BLOWOUT/HAIR TREATMENT	UNKNOWN	Ingredient From Label	ADVERSE EVENT REMARKS R EACON SITE SCALP RESPIRATO RY SYSTEM		Manufacturer	FACTS	From AE Report	COMPLAINANT, SALON OWNER REPORTS HER HAIR STYLISTS USING BRAZILIAN BLOWOUT HAIR STRAIGHTENER AND CONDITIONING LOTION PRODUCTS AND BECOMING ILL FROM THE STRONG FORMALDEHYDE FUMES SOME OF THE STYLISTS AND FEW CUSTOMERS DEVELOPED RESPIRATORY SYMPTOMS, PERSISTENT COUGHS, HEADACHES, EYE IRRITATION COMPLAINANT ATTEMPTED TO OBTAIN INGREDIENT LIST FROM COMPANY BUT WAS REFUSED CLAIMING PROPRIETARY INFORMATION ONLY THROUGH HER PHYSICIAN WAS THE LIST RELEASED COMPLAINANT CLAIMS PRODUCT CONTAINS UNSPECIFIED CHEMICAL(S) THAT IS CAUSING REACTION THIS COMPLAINT IS THE LATEST OF FOUR CALLS REC'D AT FDA PERTAINING TO BRAZILIAN BLOWOUT SINCE 5/8/09 FOLLOWING FIRST INCIDENT, SPOKE TO COMPANY SPOKESPERSON, A MR [REDACTED] WHO TOOK OVER QA AND REFORMULATION OF PRODUCTS [REDACTED] ALSO FAXED SPECIFIC INFORMATION REGARDING COMPANY OWNERSHIP AND MANUFACTURING SOURCE WHILE [REDACTED] [REDACTED] IS LISTED AS CONTRACT MANUFACTURER OF BRAZILIAN BLOWOUT IN FEI, [REDACTED] AKA [REDACTED] OWNERSHIP OF BRAZILIAN BLOWOUT IS NOT SHOWN
			ULTRASMOOTH /BLOW OUT LOTION			ADDITIONAL PRODUCT 3/31/10			Letter/Fax/Ph one		COMPANY LOCATED AT [REDACTED] [REDACTED] TELE [REDACTED] FAX THIS BRAND IS HIGHLY PUBLICIZED BY YOUNG 20-30 SOMETHING CELEBRITIES AND IS A HIGH VISIBILITY PRODUCT SPOKE TO ANOTHER COMPLAINANT AND WAS TOLD SINCE NEW AIRFLOW SYSTEM INSTALLED, INITIAL COMPLAINTS ABOUT THE PRODUCT AND FUMES HAVE ALL BUT CEASED THIS MAY BE AN ENVIRONMENTAL ISSUE THAN CHEMICAL PROBLEM 1200 HRS - SPOKE TO ANOTHER COMPLAINANT AND WAS INFORMED THAT HER STYLIST THAT BY USING LESS PRODUCT, WAS ABLE TO CONTROL THE FUMES SHE IS VERY SATISFIED WITH PRODUCT DESPITE INITIAL COMPLAINT COMPLAINT/INJURY REMARKS PRODUCT FOR PROFESSIONAL FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) COUGHING / NR / NR / NR / NR / NR, DIFFICULTY BREATHING / NR / NR / NR / NR / NR, BURNING / NR / NR / NR / NR / NR

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✓ 125880	04/14/10	04/14/10	JOHNSON & JOHNSON/GEN TLE TREATMENT HAIR PERM - REGULAR STRENGTH	UNKNOWN	Ingredient From Label	PURCHASE DATE 03/2010	 Manufacturer	 Corporate Headquarters	FACTS Letter/Fax/Ph one	From AE Report	CONSUMER PURCHASED THE GENTLE TREATMENT HAIR PERM @ WIG AND FASHIONS STORE SHE PUT THE PERM IN HERSELF AND LATER NOTICED THE LOSS OF HAIR AROUND HER TEMPLE AND PATCHES MISSING IN HER HEAD COMPLAINT/INJURY LOSS OF HAIR AROUND HER TEMPLE AND PATCHES WITHIN HER HAIR CONTACTED MANUFACTURER WHO IS REQUESTING SHE RETURN OF PRODUCT TO THEM FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) BALDING / NR / DAY(S) / 3/2010 / DAY(S) / NOW MAKING AN APPOINTMENT TO SEE A DERMATOLOGIST
✓ 129059	08/12/10	08/13/10	MIZANI RELAXER BUTTER BLEND SENSITIVE SCALP	UNKNOWN	Ingredient From Label	NA	MIZANI	Manufacturer	MW 3500	From AE Report	I UTILIZED MIZANI- LOREAL BUTTER BLEND SENSITIVE RHELAXER ON MY HAIR IN JANUARY 18, 2010 AND EXPERIENCED SEVERE SCALP BURNING, EXTREME BALDNESS AND HAIR LOSS THIS RELAXER IS DEFECTIVE PRODUCT THAT CAUSED MY HAIR LOSS I AM REQUESTING FDA TO INVESTIGATE THE MIZANI- LOREAL FOR DAMAGES CAUSED TO MY HAIR IN WHICH I VISITED MY PRIMARY CARE PHYSICIAN FOR BURNT SCALP CAUSED BY MIZANI- LOREAL RELAXER I HAVE NEVER EXPERIENCED THIS TREATMENT IN 38 YEARS OF UTILIZING HAIR CARE PRODUCTS
✓ 130998	10/12/10	10/13/10	THE BRAZILIAN BLOWOUT	UNKNOWN, FORMALDEHYDE	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Corporate Headquarters	MW 3500	From AE Report	IVE BEEN A COSMETOLOGIST FOR 30 YEARS NOW AND HAVE HAD ADVERSE AFFECTS DUE TO THE USE OF THE BRAZILIAN BLOWOUT HAIR STRAIGHTENING TREATMENT FROM JUNE 19, 2010 THROUGH OCT 12, 2010, IVE HAD NOSE BLEEDS, VERY RAW NOSE, DIFFICULTY BREATHING, PRESSURE IN CHEST, EYES WILL NOT STOP BURNING AND COUGHING, WHICH HAS BECOME PROGRESSIVELY WORSE EACH TIME THIS PRODUCT IS USED IN THE SALON THAT I'M WORKING AT IVE NOTICED WHEN THE PRODUCT IS HEATED THE SYMPTOMS GOT REALLY BAD AND SEVERAL CLIENTS AND COSMETOLOGISTS HAVE TO LEAVE THE BUILDING AFTER CALLING THE CORPORATE OFFICE OF THE BRAZILIAN BLOWOUT, I WAS TOLD THAT THE PHYSICAL EFFECTS WOULD NOT LAST AND THAT THEY WERE CAUSED BY CHEMICALS SUCH AS BEHENYL AND CETEARYL ALCOHOLS I'M CONCERNED ABOUT THE HIGH PERCENTAGES OF FORMALDEHYDE THAT HAS RECENTLY BEEN REPORTED BY  AND 

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✓ 131003	10/10/10	10/13/10	BRAZILIAN BLOWOUT	FORMALDEHYDE	Reported Ingredient	NA	BRAZILIAN BLOWOUT	Manufacturer	MW 3500	From AE Report	WE HAVE BEEN USING THE PRODUCT BRAZILIAN BLOWOUT IN THE SALON I WORK IN SINCE JUNE 2010 I HAVE PERFORMED THE PROCESS ON OTHERS AS WELL AN RECVMING THE TREATMENT MYSELF EACH TIME I HAVE EXPERIENCED BURNING/RUNING EYES AND NOSE, HEADACHES AND EXTREMELY RAW AND SORE THROAT I HAVE CONTACTED THE COMPANY SEVERAL TIMES TO QUESTION THE ADVERSE HEALTH EFFECTS THAT I AND OTHERS EXPERIENCED ONLY TO BE TOLD EACH TIME THAT THE PRODUCT IS 100 PERCENT FORMALDHYDE FREE AND SAFE I WAS ALSO TOLD THAT THE EYE BURNING HAS BEEN REPORTED AND IS DUE TO THE PERFUME THEY USE TO MAKE THE PRODUCT SMELL BETTER THEY SAID THEY HAD NO REPORTS OF HEADACHES OR SORE THROATS I HAVE SEEN THE REPORT POSTED BY OSHA STATING FORMALDHYDE LEVES BETWEEN 6 TO 10 PERCENT AND HAVE CONTACTED THEM AS WELL AS THE FDA TO TRY TO GET FURTHER INFORMATION
							UNKNOWN	Corporate Headquarters		From Other Sources	
										Preferred	
✓ 131005	10/08/10	10/13/10	BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	NA	UNKNOWN	Corporate Headquarters	MW 3500	From Other Sources	BRAZILIAN BLOWOUT WAS GETTING THIS HAIR TREATMENT FOR THE FIRST TIME AND EXPERIENCED EXTREME IRRITATION TO MY EYES THE STYLIST JUST SAID TO KEEP THEM CLOSED - SEEMED LIKE THIS HAD HAPPENED OFTEN- BUT IT WAS EXTREMELY IRRITATING AND MY EYES WERE BURNING/TEARING EVEN THROUGH CLOSED EYES NO BURNING THROAT OR HEADACHE
										Preferred	
✓ 131006	09/29/10	10/13/10	BRAZILIAN BLOWOUT SOLUTION	UNKNOWN	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Manufacturer	MW 3500	From AE Report	WATERY EYES, BREATHING PROBLEMS, BURNING SENSATIONS RELEVANT TESTS OTHER RELEVANT HISTORY NO PREEXISTING CONDITIONS
✓ 131017	10/13/10	10/14/10	BRAZILIAN BLOWOUT STRENGTH BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	NA NO LABEL	BRAZILIAN BLOWOUT	Manufacturer	MW 3500	From AE Report	THE BRAZILIAN BLOW OUT HAS MADE IT HARD FOR TO BREATHE WHILE BLOW DRYING, MY EYES AND MY CLIENTS EYES WATERED AND BURNED MY CO-WORKER BROKE OUT IN HIVES AFTER APPLYING RELEVANT TESTS / LABORATORY DATA, INCLUDING DATES REMARKS OSHA HAS REVIEWED THAT IT HAS CONTAINED 10% FORMALDEHYDE

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131040	09/28/10	09/28/10	BRAZILIAN BLOWOUT/SOL UTION PRO TREATMENT FOR SMOOTHING HAIR	UNKNOWN	Ingredient From Label	NA	[REDACTED] Corporate Headquarters		FACTS	From AE Report	COMPLAINANT REPORTED EXPERIENCE AFTER USING THE BRAZILIAN BLOWOUT SOLUTION PRO TREATMENT FOR SMOOTHING HAIR. PRODUCT IS BECOMING VERY POPULAR AT MANY SALONS. THE PROFESSIONALS WHO USE THIS PRODUCT ARE COMPLAINING THAT THE FUMES THE PRODUCT PRODUCES IS CAUSING SYMPTOMS DURING EACH USE. CLIENTS AS WELL AS SALON WORKERS ARE ALL EFFECTED AFTER APPLICATION AS STATED BELOW, HAIR IS BLOW DRIED DURING THE BLOW DRYING PROCESS, THE FUMES AND/OR VAPORS WHICH EMIT INTO THE AIR WHILE BLOWING DRYING ARE CAUSING SHORTNESS OF BREATH, CHEST PAINS, ITCHY AND WATERY EYES AND A LIST OF VARIOUS OTHER SYMPTOMS SUCH AS RASHES AND FAINTING. COMPLAINANT STATES THAT THERE ARE NO INGREDIENTS OR DIRECTIONS LISTED ON BOTTLES USED FOR TREATMENT AND THAT BOTTLES ARE DELIVERED WITHOUT OUTER PACKAGING WHICH MAY POSSIBLY CONTAIN PRODUCT INGREDIENTS PROFESSIONALS
									Letter/Fax/Ph one		WHO USE THE PRODUCT ARE PROVIDED A TRAINING COURSE PRODUCT IS APPLIED TO HAIR OF CLIENTS BASED ON INFORMATION OBTAINED IN TRAINING VIDEO. COMPLAINANT BELIEVES COMPANY DELIBERATELY IS ELIMINATING THE INGREDIENTS SINCE PRODUCT IS NOT FDA APPROVED. THIS WILL KEEP THEM UNDER THE RADAR AS LONG AS POSSIBLE PER COMPLAINANT. SALONS PROVIDE MASKS FOR THEIR CLIENTS AND SALON WORKERS HOWEVER THE FUMES TRAVEL THROUGHOUT THE SALON AND EFFECT THOSE WHO ARE NOT USING THE PRODUCT. SYMPTOMS LAST FOR ONE HOUR OR MORE AND PERSONS ARE IMMEDIATELY EFFECTED BY FUMES. COMPLAINT/INJURY REMARKS: DIRECTIONS TAKEN DIRECTLY FROM COMPANY WEBSITE.
							[REDACTED] Distributor		FACTS	From AE Report	ARE AS FOLLOWS: AFTER TOWEL DRYING, YOUR CERTIFIED BRAZILIAN BLOWOUT STYLIST WILL DIVIDE YOUR HAIR INTO SECTIONS AND BEGIN TO COMB THE BRAZILIAN BLOWOUT PROFESSIONAL TREATMENT THROUGH EACH SECTION OF THE HAIR FROM ROOT TO TIP, LIGHTLY DUSTING EACH SECTION WITH THE SOLUTION. SOLUTION WILL SURROUND EACH HAIR SHAFT WITH PROTECTIVE PROTEIN LAYERS TO SMOOTH AND FLATTEN THE CUTICLE. STYLIST WILL THEN BLOW-DRY YOUR HAIR AS STRAIGHT AS POSSIBLE WITH A FLAT OR ROUND BRUSH. ONCE THE HAIR IS DRY, THE STYLIST WILL DIVIDE THE HAIR INTO FOUR SECTIONS AND BEGIN USING A FLAT IRON TO

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									Letter/Fax/Ph one	From AE Report	FURTHER STRAIGHTEN THE HAIR IN 2-3 INCH SECTIONS ONCE COMPLETE, THE STYLIST WILL RINSE THE HAIR (NO SHAMPOO), TOWEL-DRY AND APPLY THE BRAZILIAN BLOWOUT MASQUE TO FURTHER SEAL IN THE PROFESSIONAL FORMULATION AFTER 60 SECONDS, THE STYLIST WILL RINSE THE HAIR ONCE AGAIN AND TOWEL DRY THE STYLIST WILL THEN APPLY THE BRAZILIAN BLOWOUT SMOOTHING SERUM TO FURTHER SEAL THE CUTICLE AND ASSIST IN DETANGLING THE HAIR PRIOR TO THE FINAL BLOW DRY THE STYLIST WILL THEN BLOW DRY THE HAIR STRAIGHT ONE FINAL TIME AND STYLE AS DESIRED FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) EYE IRRITATION / 1-3 / HOUR(S) / NR / IMMEDIATE/ ITCHY AND WATERY EYES, DIFFICULTY BREATHING / 1-3 / HOUR(S) / NR / IMMEDIATE/ SHORTNESS OF BREATHE, ASTHMA LIKE SYMPTOMS, NEC - IDENTIFY IN REMARKS / 1-3 / HOUR(S) / NR / IMMEDIATE/ SOMETIMES CAUSES RASH ON SCALP AND FAINTING, CHEST PAIN / 1-3 / HOUR(S) / NR / IMMEDIATE/ NR
✓ 131251	10/18/10	10/20/10	BRAZILIAN BLOWOUT SOLUTION	UNKNOWN, FORMALDEHYDE	Alleged Problem Ingredient not on label	NA	CADIVEU PROFESSIONAL	Manufacturer	MW 3500	From Other Sources	ON SEPTEMBER 16, 2010, I HAD THE BRAZILIAN BLOWOUT TREATMENT AT SALON [REDACTED] IN [REDACTED] TO STRAIGHTEN MY NATURALLY WAVY HAIR WITHIN FIVE DAYS OF THE TREATMENT I BEGAN LOSING LARGE AMOUNTS OF HAIR, AT LEAST THREE-FOUR TIMES WHAT I WOULD USUALLY LOSE IN A DAY IN ONE MONTH, I HAVE EXPERIENCED ABOUT A 40% VOLUME LOSS IN MY HAIR AND IT CONTINUES TO FALL OUT AT THE SAME ALARMING PACE I RESEARCHED THIS TREATMENT AND SPECIFICALLY ASKED FOR IT BECAUSE THE MARKETING MATERIALS, AND SALON STYLIST, SAID THE PRODUCT WAS FREE OF FORMALDEHYDE, UNLIKE MANY OTHER TREATMENTS ON THE MARKET I WOULD NOT HAVE GOTTEN THE TREATMENT AT ALL IF I KNEW IT HAD FORMALDEHYDE IN IT MY HAIR CONTINUES TO FALL OUT AND I AM VERY CONCERNED ABOUT MY HEALTH, FIRST, AND THE EMOTIONAL DAMAMAGE THIS VERY EXPENSIVE AND SEEMINGLY MISLEADING PRODUCT MAY HAVE CAUSED TO MY HAIR AND SCALP OTHER RELEVANT HISTORY KNOWN ALLERGY PENICILLIN PRESCRIPTION DRUGS AT TIME OF INCIDENT NUVA RING BIRTH CONTROL DEVICE
					Ingredient From Label					From Other Sources	I HAD THE BRAZILIAN BLOWOUT HAIR TREATMENT APPLIED TO MY HAIR ON 7/21/2010 FROM A REPUTABLE SALON IN [REDACTED]

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131499	10/21/10	10/22/10	BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	DATES OF USE 07/21/2010— 07/21/2010 AND 08/13/2010— 08/13/2010	UNKNOWN	Corporate Headquarters	MW 3500	Preferred	I IMMEDIATELY EXPERIENCED BURNING EYES, BURNING AND RUNNING NOSE AND A BURNING THROAT THE SYMPTOMS CONTINUED AFTER THE TREATMENT AFTER 2 DAYS THERE WAS EVIDENCE OF FRIZZ IN THE MID SECTION OF MY HAIR, SO ON 8/13/2010 I RETURNED TO THE SALON FOR A DO OVER OF THE BAD SECTIONS -THE STYLIST ENDED UP REDOING THE ENTIRE HAIR-WHICH PUT ME IN CONTACT WITH THE FUMES LONGER- I HAD REMOVED MY CONTACT LENSES, WORE GLASSES, PUT SALINE IN MY NOSE TO TRY TO NEGATE THE ADVERSE REACTIONS THIS TIME THE REACTIONS WERE MORE SEVERE AND I WAS IN AGONY DURING AND AFTER THE APPOINTMENT MY EYES, ESPECIALLY THE LEFT ONE CONTINUED TO BURN AND I ENDED UP AT THE OPTOMETRISTS OFFICE WHERE I WAS DIAGNOSED WITH AN CORNEAL ABRASION I HAD ALWAYS WORN MY CONTACT LENSES FOR 16 HOURS A DAY AND IT TOOK SEVERAL WEEKS TO BUILD BACK UP MY WEARING TIME I STILL HAVE ISSUES WITH BURNING, STINGING EYES OTHER RELEVANT HISTORY I HAVE ALWAYS HAD SENSITIVITIES TO SMELLS
131532	10/27/10	10/27/10	BRAZILLIAN BLOWOUT/SOL UTION PRO TREATMENT FOR SMOOTHING HAIR	UNKNOWN	Ingredient From Label	NA		Dealer	FACTS	From Other Sources	39 YEAR OLD FEMALE COMPLAINANT REPORTED INCIDENT AFTER USING BRAZILIAN BLOWOUT SOLUTION PRO TREATMENT FOR SMOOTHING HAIR COMPLAINANT HAS NO KNOWN ALLERGIES, NO MEDICAL CONDITIONS AND HAS NOT HAD ANY REACTION TO HAIR TREATMENTS IN PAST COMPLAINANT FIRST RECEIVED HAIR TREATMENT AT SALON SIX MONTHS AGO SHE WAS ADVISED THAT PROCESS TO SMOOTH HAIR TAKES THREE DAYS AND PRODUCT WAS TO REMAIN IN HAIR AFTER SALON VISIT AFTER THE THIRD DAY SHE WAS INSTRUCTED TO WASH OUT TREATMENT AFTER WASHING/RINSING PRODUCT OUT OF HER HAIR COMPLAINANT IMMEDIATELY NOTED HAIR LOSS AND HER HAIR WAS VERY TANGLED OVER TIME HAIR BECAME THIN AND SHE EXPERIENCED MORE HAIR LOST STYLIST INFORMED COMPLAINANT THAT HER HORMONES FROM CHILD BIRTH WERE CAUSE OF HER SYMPTOMS AND THAT SHE SHOULD NOT BE CONCERNED COMPLAINANT HAD A CHILD 2 1/2 YEARS AGO COMPLAINANT VISITED SALON FOR A SECOND TREATMENT TWO WEEKS AGO IT WAS SUPPOSE TO LEAVE HER HAIR HEALTHIER, SHINIER AND LESS FRIZZY INSTEAD SHE EXPERIENCED EVEN FURTHER HAIR LOST AND NOTED IT WAS VERY TANGLED STYLIST OFFERED KERATIN TREATMENT
									Letter/Fax/Ph one		
								Distributor	FACTS	From AE Report	
									Letter/Fax/Ph one		
			UNKNOWN	Manufacturer	FACTS	From Other Sources	AND PROTEIN MASKS TO CORRECT THE SYMPTOM AS SHE WAS TOLD THERE IS NO WAYS TO ELIMINATE IT ONLY PREVENT FURTHER DAMAGE HAIR LOSS IS A PERSISTENT SYMPTOM COMPLAINANT STATED THAT SHE HAD NO CONCERNS OR ISSUES DURING THE APPLICATION PROCESS FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) HAIR BREAKAGE / NR / NR / NR / IMMEDIATE / HAIR LOST				
					Letter/Fax/Ph one	Preferred					

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✓ 131679	10/26/10	10/28/10	GLOBAL HAIR TAMING SYSTEM WITH JUVEXIN	UNKNOWN	Ingredient From Label	NA	UNKNOWN	Corporate Headquarters	MW 3500	From Other Sources	GLOBAL KERATIN HAIR TAMING SYSTEM WITH JUVEXIN IS THE HAIR STRAIGHTENING SYSTEM I APPLIED TO MY CLIENT THIS PRODUCT DOES CONTAIN FORMALDEHYDE AND WHEN FLAT IRONED @400 DEGREES OR MORE LETS OFF A TOXIC VAPOR THIS STEP HAS TO BE TAKEN TO SEAL KERATIN INTO HAIR THE FIRST TIME I USED THE PRODUCT I COULD - TASTE IT IN MY THROAT AND SMELL IT FOR HOURS AFTER THE SERVICE THE SECOND TIME I USED THE PRODUCT MY TONGUE WAS TINGLING AND NUMB FOR A COUPLE OF HOURS AND MY EYES BURNED THIS PRODUCT IN VERY DANGEROUS, I AM CONCERNED ABOUT STYLIST AND CUSTOMER'S WELL BEING AFTER REPEATED USE I WILL NEVER AGAIN USE THIS PRODUCT, BUT MY CO WORKERS ARE STILL USING IT THE FORMALDAHYDE VAPORS ARE IN THE SALON FOR EVERYONE THE BREATHE PLEASE REVIEW THIS PRODUCT
✓ 131686	10/22/10	10/28/10	SIMPLY SMOOTH/BRAZI LIAN BLOWOUT TREATMENT	UNKNOWN	Ingredient From Label	NA	AMERICAN CULTURE	Manufacturer	MW 3500	From Other Sources	<p>I RECEIVED A BRAZILIAN BLOWOUT TREATMENT AT SALON IMMEDIATE EFFECTS BURNING OF SCALP, EXPOSED SKIN, EYES, NOSE, THROAT & CHEST, HEADACHE, TIGHTNESS FEELING TO CHEST LIKE BRONCHIAL IRRITATION NEXT DAY EFFECTS, SEVERE HEADACHE, DIZZINESS, NAUSEA/VOMITING, FEVER, RASH, BLURRED VISION IN RIGHT EYE EFFECTS CONTINUED TO WORSEN FOR NEXT 3 DAYS WENT TO ER WHEN VOMITING WOULDN'T STOP & FEVER INCREASED ADMITTED TO HOSPITAL WITH 102F FEVER, VOMITING, DIARRHEA, DEHYDRATION, RAPID HEART RATE & ELEVATED BLOOD PRESSURE STAYED IN HOSPITAL FOR 3 DAYS TOTAL - CONTINUED SYMPTOMS RELEASED FROM HOSPITAL AFTER VOMITING & FEVER CONTROLLED WITH MEDICATIONS SYMPTOMS CONTINUED WITH SLOW IMPROVEMENT NEXT 5 DAYS ONGOING CHEST, THROAT & EYE IRRITATION I AM AWAITING LAB TEST RESULTS FROM URINE, BLOOD, & STOOL SAMPLES TAKEN THROUGHOUT THE 3 DAYS RELEVANT TESTS AWAITING LAB RESULTS FROM 3 DAY HOSPITAL STAY - 10/12/2010 - 10/14/2010 - SAMPLES INCLUDE BLOOD, URINE, & STOOL XRAY TAKEN OF CHEST IN ER -10/12/2010-</p> <p>OTHER RELEVANT HISTORY NO PREEEXISTING CONDITIONS RELATED TO EVENT OVERALL HEALTH IS GOOD LAPROSCOPIC SUPRACERVICAL HYSTERECTOMY DUE TO FIBROID RESCHEDULED DUE TO EVENT - NO SYMPTOMS RELATED TO THIS ILLNESS</p>

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✓ 131687	10/22/10	10/28/10	BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Corporate Headquarters	MW 3500	From AE Report	I HAVE HAD THE BRAZILIAN BLOWOUT DONE THREE TIMES IN THE PAST YEAR AND 2 OF THE 3 TIMES, I HAVE HAD STINGING WAYERY EYES, HEADACHES AND NOSE BURNING FROM THE FUMES EVEN WHEN THE HEAT FROM THE STRAIGHT IRON WAS NOT PRESENT I STILL HAD BURNING/STINGING EYES OTHER RELEVANT HISTORY PREVIOUS SMOKER -QUIT 6 YEARS AGO- CROHN'S DISEASE
✓ 131804	11/05/10	11/05/10	KERATIN HAIR TREATMENT	UNKNOWN, METHYLENE GLYCOL	Ingredient From Label	NA	UNKNOWN	Manufacturer	MW 3500	From Other Sources	THE COMPLAINANT IS A HAIRDRESSER WHOSE RESEARCH INDICATES THAT MANY BRANDS OF KERATIN HAIR TREATMENT CONTAIN METHYLENE GLYCOL, WHICH WHEN HEATED(E G , IN THE HAIR TREATMENT, HAIR DRYING PROCESS) RELEASES FORMALDEHYDE GAS THE COMPLAINANT USES THESE HAIR TREATMENTS IN HER JOB AND HAS EXPERIENCED LOSING HER VOICE, LUNG IRRITATION, THROAT IRRITATION, SINUS IRRITATION, SKIN IRRITATION, HEADACHES, AND DIZZINESS SHE HAS BEEN HOSPITALIZED AND HAS REPORTED THE PROBLEM TO [REDACTED]
					Reported Ingredient					Preferred	
									FACTS	From AE Report	COMPLAINANT (47 Y/O FEMALE) SUFFERED SEVERE ADVERSE REACTION FROM USE OF BRAZILIAN BLOWOUT ("BB") AT SALON ON 9/22/10 COMPLAINANT WENT TO [REDACTED] SALON IN [REDACTED] TO HAVE HAIR STYLED USING BB STRAIGHTENER & CONDITIONER. STYLIST, [REDACTED] INSTRUCTED COMPLAINANT TO CONTINUE USING SHAMPOO, CONDITIONER AND MASK ON HER HAIR FOR EIGHT DAYS, THEREAFTER RETURN TO SALON FOR RINSE AND FINAL STYLING BY DAY 7 COMPLAINANT HAD BECOME SO ILL SHE HAD TO REMOVE THE CONDITIONER WHILE RINSING IN THE SHOWER, SHE PULLED APPROX 2.5 FEET OF HAIR FROM HER HEAD, HAIR CONTINUED TO FALL OFF AS SHE CONTINUED TO RINSE BLISTERS ALSO DISCOVERED ON THE BACK OF HEAD DURING THIS WAIT PERIOD COMPLAINANT DEVELOPED SEVERE STABILITY PROBLEMS (SEVERE DIZZINESS) THAT PROGRESSED TO POINT SHE WAS UNABLE TO WALK W/O ASSISTANCE AND HAD TO RELY ON WALKER CONCURRENT TO THIS DEBILITATING CONDITION, ON OR ABOUT DAY 3, COMPLAINANT BEGAN TO VOMIT VOMITING PERSISTED AND CONTINUED TO THIS DAY, ALBEIT FREQUENCY DOWN TO 3X (11/9/10) ON 9/29 COMPLAINANT RETURNED TO SALON PEOPLE NO EFFORT WAS MADE TO REMEDY

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132033	11/09/10	11/09/10	BRAZILIAN BLOWOUT/HAIR STRAIGHTENIN G & CONDITIONER	UNKNOWN	Ingredient From Label	NA			Letter/Fax/Ph one	From AE Report	HER PROBLEM EXCEPT OFFERED APOLOGIES. COMPLAINANT THEN WENT TO LOCAL URGENT CARE. PHYSICIAN EXAMINED AND NOTED HAIR LOSS, BLISTERS ON SCALP AND ULCER FORMATION IN HER MOUTH. MEDS RX TO TX NAUSEA. COMPLAINANT'S SYMPTOMS BECAME PROGRESSIVELY WORSE IN THE ENSUING DAYS. DIZZINESS INCREASED, SHE CONTINUED TO VOMIT EVERY DAY -- AS OFTEN AS 15-30X. COMPLAINANT COULD NOT HOLD FOOD OR WATER. HER WEIGHT WENT FROM 112 LBS TO PRESENT 88 LBS. ON 10/18 COMPLAINANT RETURNED TO URGENT CARE AND ALSO WENT TO DENTIST. PERSISTENT VOMITING HAD SEVERELY DAMAGED HER TEETH AND GUM, MICRO-FISSURES APPEARED ON SOME OF HER TEETH AND GUM LINE BLEEDING WAS PRESENT. COMPLAINANT NEVER HAD ANY DENTAL PROBLEMS UNTIL EXPOSURE TO BB PRODUCTS. DENTAL X-RAYS CAN CORROBORATE TEETH CONDITION. ON 10/19 COMPLAINANT UNDERWENT 4 HRS OF
									FACTS	From AE Report	ORAL SURGERY TO REPAIR DAMAGE. (CONTINUE REMARKS) COMPLAINT/INJURY REMARKS (CONTINUED FROM COMPLAINT DESC) ON 10/20 COMPLAINANT COULD NOT STOP VOMITING AND WAS ADMITTED TO [REDACTED] ANTI-NAUSEA MED ADMINISTERED. BY THIS TIME COMPLAINANT FOUND INFORMATION THAT POSSIBLE PRESENCE OF FORMALDEHYDE IN BB PRODUCTS AND CONVEYED HER CONCERNS TO ATTENDING PHYSICIANS. [REDACTED] DID NOT CONDUCT ANY LABS TESTS. ON 10/29, 11/1, 2, 4 AND 9, COMPLAINANT WENT TO HER PULMONOLOGIST (PRIMARY PHYSICIAN) AND EXPLAINED PRE/POST USE OF BB PRODUCTS WHEN SYMPTOMS APPEARED. DURING EACH PHYSICIAN VISIT, BLOOD, URINE TESTS WERE ADMINISTERED. EACH SUCCESSIVE TEST REVEALED HIGH WHITE BLOOD COUNT, HIGH CO2 PRESENCE, ABNORMAL LIVER ENZYMES, HIGH FOLIC ACID, ELEVATED LYMPH NODES, HIGH CORTISOL LEVEL (USUALLY ASSOCIATED WITH STRESS). 11/10/10 - 0815 HRS. F/U CALL TO COMPLAINANT. PULMONOLOGIST PERFORMED A PFT (PULMONARY FUNCTION TEST) AND FAILED. LAB TESTS WILL BE PERFORMED THURSDAY. COMPLAINANT HAS CHEST TIGHTNESS, SEVERE RESPIRATORY
							[REDACTED]	Manufacturer			DISTRESS, RAPID HEART BEATING. VOMITING IS NOT LESS FREQUENT (APPROX 3X/DAY). COMPLAINANT ALSO MENTIONED THAT DURING 8 DAY PERIOD, WHENEVER THE HAIR IS WARM, I.E., AFTER HOT RINSE, CHEMICAL ODOR VERY STRONG.

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									Letter/Fax/Ph one	From AE Report	THIS EFFECT CONTINUED UNTIL COOLED OFF IMPORTANT NOTE STYLIST GAVE COMPLAINANT BOTTLES OF SHAMPOO, CONDITIONER AND CONDITIONING MASK TO USE DURING 8 DAY PERIOD. COMPLAINANT SAID NO USE DIRECTIONS WERE GIVEN. PRODUCTS WERE USED APPROX 2-3X DURING 8 DAY PERIOD. EACH APPLICATION RESULTED IN SEVERE BURNS AND BLISTERS AND HAIR LOSS. COMPLAINANT HAS ALL THREE PRODUCTS AVAILABLE FOR SAMPLING. OTHER CLINICAL PROVIDERS COMPLAINANT CONSULTED [REDACTED] MD URGENT CARE, [REDACTED] DOS 9/29, 10/1, 10/18, [REDACTED] MD (DERMATOLOGIST) [REDACTED] DOS 10/1/10 (BRIEF CONSULT AND WAS TOLD FORMALDEHYDE POISONING NON-EXISTENT DR [REDACTED] DDS, [REDACTED] (ADDRESS REQ'D) FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) DIZZINESS OR PROBLEMS WITH BALANCE / NR
✓ 132039	11/12/10	11/12/10	BRAZILIAN BLOWOUT/HAIR STRAIGHTENER	UNKNOWN	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Corporate Headquarters	Letter/Fax/Ph one	From AE Report	THE COMPLAINANT IS A HAIRDRESSER WHO WORKS WITH BRAZILIAN BLOWOUT HAIR STRAIGHTENER, WHICH SHE REPORTS GIVES OFF FORMALDEHYDE FUMES WHEN HEATED BY THE IRONING PART OF THE HAIR TREATMENT PROCESS. SHE REPORTED THAT HER EYES BURN, HER NOSE BURNS AND SHE EXPERIENCED NOSEBLEEDS, THROAT SWELLINGS, AND HEADACHES.
✓ 132202	11/17/10	11/17/10	BRAZILIAN BLOWOUT/HAIR STRAIGHTENER	UNKNOWN	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Manufacturer	MW 3500	From AE Report	THE COMPLAINANT IS A HAIRDRESSER WHO REPORTS ADVERSE SYMPTOMS RELATED TO BRAZILIAN BLOWOUT AND KERATIN COMPLEX HAIR STRAIGHTENING PRODUCTS. HAIR TREATED WITH THE PRODUCTS IS HEATED WITH A FLAT IRON TO 400 DEGREES, WHICH RESULTS IN RELEASE OF FORMALDEHYDE VAPOR. THE COMPLAINANT EXPERIENCED HEADACHES, EYE IRRITATION, AND CONGESTED SINUSES.
			KERATIN COMPLEX/HAIR STRAIGHTENER				KERATIN COMPLEX			From Other Sources	

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✓ 132275	11/10/10	11/10/10	BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	NA	CADIVEU PROFESSIONAL	Manufacturer	MW 3500A	From Other Sources	<p>FDA, MY NAME IS [REDACTED] I WAS EMPLOYED AT [REDACTED] A WORLDWIDE HAIR SALON, AND LEFT RECENTLY AFTER BEING EXPOSED TO A CHEMICAL CONTAINED IN THE BRAZILIAN BLOWOUT PRODUCT WHICH IS BEING LOOKED INTO FOR IT'S FORMALDEHYDE CONTENT I AM STILL SYMPTOMATIC WITH NAUSEA, STUFFINESS, FATIGUE, NASEL BLOCKAGE, CHEST PAIN, DIFFICULTY BREATHING I WAS PERFORMONG THE BRAZILIAN BLOW OUT PRODUCT IN THE [REDACTED] FOR ABOUT THE 5TH TIME ON A CLIENT, EXCLUDING THE 2 TIMES I RECEIVED IT, AND BECAME VERY ILL, WHITE IN THE FACE AND FELT AS IF I WAS GOING TO PASS OUT DIRECTLY FOLLOWING THIS I HAD A COUGH, BLOOD COMING FROM MY NASEL PASSAGE, CONGESTION AND THE SYMPTOMS LISTED ABOVE I AM STILL SICK AND NOT GETTING GOOD ENOUGH CARE THROUGH [REDACTED] WORKMENS COMP I HAVE HAD TO SEEK MY OWN MEDICAL DOCTOR FOR PROPER</p> <p>CARE AND PAY OUT OF POCKET AND I'M STILL NOT WELL PLEASE HELP [REDACTED] I WANT TO REPORT THIS INCIDENT AND GET ANY INFORMATION TO FOLLOW UP SINCERELY, [REDACTED]</p> <p>RELEVANT TESTS I HAVE HAD X-RAYS WITHIN THE FIRST FEW WEEKS I HAVE BEEN SEEN BY AN EMERGENY ARE DOCTOR SINCE 9/29/2010 3 TIMES AND FINALLY TO AN WORKMENS COMP ENT ON THE 27TH WHOM WHICH DID NOT SCOPE ME EVEN AFTER I COMPLAINED OF THESE SYMPTOMS AND SAID HE HAD NO OBJECTIVE FINDINGS I HAVE GOTTEN A 2ND OPINION THAT STATES OTHERWISE. I AM STILL AWAITING APPROVAL FOR A CT SCAN OF MY NASEL PASSAGE WAY THAT WAS SUPPOSED TO BE APPROVED OVER A WEEK AGO-THEY HAVE 3 DAYS TO APPROVE-AND I HAVE STILL NOT BEEN ABLE TO GET APPROVAL AFTER CALLING MY ADJUSTER, THE ACTUAL INSURANCE COMPANY, AND THE PLACE WHERE THEY PERFORM THE CT SCAN NO LUCK AND STILL ILL OTHER RELEVANT HISTORY I AM STILL SICK WITH NASEL CONGESTION AND BLOCKAGE, HEADACES, NAUSEA, DIZZINESS, FATIGUE, STIFFINESS, DIFFICULTY BREATHING, VIRTAGO I JUST FINISHED MY FOURTH ANTIBIOTIC AND I'M STILL NOT WELL</p>
✓ 132276	11/07/10	11/10/10	BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	NA	[REDACTED]	Distributor	MW 3500	From AE Report	<p>I RECENTLY HAD A BRAZILIAN BLOWOUT- WITH THE PRODUCT OF THE SAME NAME- I DID HAVE NOTICIABLE EYE IRRITATION- WHERE I FELT LIKE MY EYES WERE BURNING</p>




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✓ 132278	11/04/10	11/10/10	BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	NA	UNKNOWN	Manufacturer	MW 3500	From AE Report	USE OF BRAZILIAN BLOWOUT BRAND HAIR TREATMENT IN A PROFESSIONAL SALON HAD THE FOLLOWING EFFECTS - SIGNIFICANT EYE IRRITATION - HEADACHE
✓ 132280	11/02/10	11/10/10	BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	NA	CADIVEU PROFESSIONAL	Manufacturer	MW 3500	From Other Sources	LOSS OF TASTE AND SMELL DURING THE WEEK SHE HAD A BRAZILIAN BLOWOUT RELEVANT TESTS HAS HAD MRI, CT SCAN AND BLOOD WORK SAW PRIMARY DOCTOR, ENT AND SPECIALIST IN LOSS OF TASTE AND SMELL
✓ 132284	11/03/10	11/10/10	BRAZILIAN BLOWOUT/ACAI ANTI-FRIZZ CONDITIONER BRAZILIAN BLOWOUT/ACAI ANTI-FRIZZ SHAMPOO	UNKNOWN	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Corporate Headquarters	MW 3500	From AE Report	I HAVE RECEIVED 3 BRAZILIAN BLOWOUTS SINCE FEBRUARY OF 2010 RIGHT AFTER ONE I HAD ON THE DAY OF THE SUPERBOWL IN FEBRUARY OF 2010 I WAS GETTING READY TO GO TO THE [REDACTED] FOR THE SUPERBOWL PARTY OUT OF THE BLUE RIGHT BEFORE I WAS ABOUT TO GET ON THE SHUTTLE I FAINTED AND MY FRIEND CAUGHT ME THANK GOODNESS I WAS OUT FOR ABOUT 5 HOURS I CONSTANTLY NOW HAVE HEADACHES AND MY RIGHT EYE DOES NOT STOP WATERING I KNOW NOW THAT I FAINTED BECAUSE OF THE BLOWOUT AND IT EXPLAINS WHY MY EYE WATERS I AM VERY ANGRY AND UPSET BECAUSE OF THE AMOUNT OF MONEY I SPENT AT THE SALON IN [REDACTED] THAT I WENT TO I AM CURRENTLY IN THE AIR FORCE AND COULDN'T EXPLAIN TO THEM WHY I HAD FAINTED AND I AM CURRENTLY BEING TREATED BECAUSE I AM NAUSEOUS EVERY DAY AND THEY DON'T KNOW WHY I ALWAYS USE THE SHAMPOO AND CONDITIONER AND JUST STOPPED TODAY BECAUSE MY AUNT CALLED ME AND TOLD ME ABOUT THE ADVERSE AFFECTS THE BRAZILIAN BLOWOUT CAN CAUSE
✓ 132287	11/05/10	11/10/10	BRAZILIAN KERATIN TREATMENT	UNKNOWN	Ingredient From Label	NA	M&M INTERNATIONA L, INC	Manufacturer	MW 3500	From Other Sources	I RECEIVED THE BRAZILIAN KERATIN TREATMENT [REDACTED] AT A SALON IN [REDACTED] DURING THE TIME OF MY HAIR TREATMENT, I EXPERIENCED EYE IRRITATION AND A BAD SMELL THE STYLIST PERFORMING THE TREATMENT RELAYED TO ME THAT SHE WAS GOING TO OPEN THE WINDOWS BECAUSE OF THE STRONG ODOR AND THE LACK OF VENTILATION ONCE AWAY FROM THE SALON, MY EYES DID NOT SEEM TO BOTHER ME, BUT MY HAIR TOOK ON A GREASY LOOK/GREASY FILM THAT DID NOT GO AWAY UNTIL AFTER TWO WEEKS OF WASHING I SEEM TO HAVE A LOT OF DRYNESS WITH THIS TREATMENT RELEVANT TESTS [REDACTED] CONDUCTED TESTS OF ALL HAIR

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											SMOOTHING TREATMENTS IN OCTOBER 2010 OTHER RELEVANT HISTORY I DO HAVE SEASONAL ALLERGIES AND I AM ALLERGIC TO MANY MEDICATIONS I DID HAVE A SMOOTHING TREATMENT PRIOR TO THE ONE IN JUNE 2010 MY FIRST SMOOTHING TREATMENT WAS PERFORMED ON DECEMBER 5, 2009 IN A [REDACTED] SALON AND WAS THE BRAZILIAN BLOWOUT I DO NOT RECALL HAVING ADVERSE EFFECTS TO THE TREATMENT NOR DO I RECALL A BAD SMELL THE TREATMENT SEEMED TO MAKE MY HAIR SMOOTHER AND SHINIER
✓ 132289	11/05/10	11/10/10	BRAZILIAN BLOWOUT - NEW FORMULA	UNKNOWN	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Manufacturer	MW 3500	From AE Report	I HAD THE BRAZILIAN BLOWOUT DONE TO MY HAIR ON JULY 1, 2010, AND THEN MY HAIR STARTED FALLING OUT AND CONTINUES TO DO SO I HAVE BEEN TO MY DERMATOLOGIST AND HE CONFIRMS THAT MY HAIR FOLLICLES HAVE BEEN DAMAGED MY DERMATOLOGIST TOLD ME THAT I COULD PROBABLY LOSE MY HAIR FOR UP TO A YEAR I HAVE FOUND OTHER PEOPLE THAT ARE HAVING THE SAME PROBLEM IN A BLOG ONLINE THIS HAS BEEN EMOTIONALLY DEVASTATING FOR ME AND IT WILL TAKE YEARS FOR MY HAIR TO RETURN TO ITS PRIOR STATE
✓ 132303	11/09/10	11/12/10	BRAZILIAN BLOWOUT	UNKNOWN, FORMALDEHYDE	Alleged Problem Ingredient not on label	NA	BRAZILIAN BLOWOUT	Manufacturer	MW 3500	From AE Report	WE WOULD LIKE TO REPORT OUR COMPLAINTS ABOUT THE BRAZILIAN BLOWOUT PRODUCT WE'VE BEEN MONITORING [REDACTED] [REDACTED] REPORTS AND FINDINGS ON THE PRODUCT AND BECAUSE OF THE CONTROVERSARY, WE DID OUR OWN AIR QUALITY TEST IN THE SALON WHILE DOING A SERVICE THE LAB JUST REPORTED THAT THERE WAS THE HIGHEST LEVELS OF FORMALDEHYDE THEY'VE EVER SEEN IN A PRODUCT AND IT IS POTENTIALLY AN EXTREMELY DANGEROUS PRODUCT IF NOT USED PROPERLY IN NONE OF THE TRAINING OR WHEN PURCHASING THE PRODUCT DID BB NOTIFY US THAT THERE IS FORMALDEHYDE IN THE INGRED THE BOTTLE ACTUALLY SAYS 'FORM FREE' RIGHT ON THE BOTTLE AND THEY DID NOT NOTIFY US THAT WE SHOULD HAVE EXTENSIVE VENTILATION SYSTEMS IN PLACE TO DO THIS SERVICE WITHOUT ENDANGERING THE STYLIST OR CLIENTS HEALTH BESIDES OUR AIR QUALITY TEST, [REDACTED] HAS VERIFIED THAT THE PRODUCT HAS BETWEEN 6-10% FORM IN THE INGRED WE HAVE ASKED THE COMPANY NUMEROUS TIMES FOR A INGRED LIST WHICH THEY HAVE REFUSED TO PROVIDE US RELEVANT TESTS [REDACTED]

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					Ingredient From Label						WEBSITE HAS EXTENSIVE DATA ON THEIR TESTS AND RESULTS OF OVER 6% FORM THE LAB THAT DID OUR AIR QUALITY TESTS PHONE # IS [REDACTED] AND HAS AGREED TO TALK WITH ANYONE NEEDING INFO ABOUT OUR TEST OTHER RELEVANT HISTORY SO FAR OUR STYLISTS HAVE NOT NOTICED ANY MAJOR MEDICAL CONDITIONS WE HAVE EXPERIENCED SHORT TERM EYE IRRITATION, BREATHING PROBLEMS, AND HEADACHES WHILE DOING THE SERVICE AND UP TO 12HRS AFTER WE ARE UNSURE AND CONCERNED WITH THE LONG TERM HEALTH EFFECTS
✓ 132391	11/10/10	11/17/10	BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	NA	UNKNOWN	Corporate Headquarters	MW 3500	From Other Sources Preferred	HAD BRAZILIAN BLOWOUT HAIR STRAIGHTENING DONE DURING PROCESS EXPERIENCED BURNING EYES AND REQUESTED SALON TO OPEN THE DOOR FOR BETTER VENTILATION ALSO EXPERIENCED A FUNNY TASTE SENSATION ON MY TONGUE DURING THE PROCESS
✓ 132453	09/20/10	09/20/10	COPPOLA/KERA TIN COMPLEX	UNKNOWN	Ingredient From Label	ADVERSE EVENT DATE OCT 2009 TO PRESENT	KERATIN COMPLEX	Manufacturer	FACTS	From Other Sources Letter/Fax/Ph one	LOG # [REDACTED] - HAIR LOSS ABOUT THE SIZE OF A SILVER DOLLOR ON THE TEMPLE AREAS OF THE HEAD FROM THE USE OF KERATIN COMPLEX HAIR TREATMENT BY COPPOLA FOR FRIZZ AT THE [REDACTED] FIRST TREATMENT JUNE/JULY 2010 AND SECOND TREATMENT OCTOBER 2009 AND HAIR LOSS BEGAN AFTER JANUARY 2010 COMPLAINANT HAS SEE VARIOUS DERMATOLOGIST FOR SCAPLE INJECTIONS OF STEROIDS WITH SOME HAIR GROWTH COMPLAINANT HAS SEEN ON THE INTERNET SIMILAR HAIRLOSS BY USERS OF KERATIN HAIR TREATMENT COMPLEX SOLUTIONS MANUFACTURED BY COPPOLA OR OTHER COMPANIES THAT CONTAIN FORMALDEHYDE OR FORMS HAIR KILLING CHEMICALS AT HIGH TEMPERATURES SUCH AS WHEN A HAIR BLOWER OR HAIR CURLING IRON IS USED COMPLAINANT DID NOT EXPLAIN THE TWO MONTH SPAN BETWEEN OCT 2009 AND JAN 2010 WHEN HAIR LOSS WAS BEING OBSERVED FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) HAIR BREAKAGE / NR / NR / SEE ABOVE / NR / CONTINUES

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✓ 132586	10/10/10	11/19/10	NATURAL KERATIN SMOOTHING TREATMENT	UNKNOWN	Ingredient From Label	NA	COPOMON ENTERPRISES LLC	Manufacturer	MW 3500	From Other Sources	NATURAL KERATIN HAIR STRAIGHTENING TREATMENT HAS METHYLENE GLYCOL WHEN BLOWDRYING HIGH HEAT FLATIRON AT 450 DEGREES RELEASE FORMALDEHYDE FILMS PROCESS TAKES HOURS LONG WAS NOT TOLD TO WEAR MASK OR HAD A FAN FOR VENTILATION, NO GLOVES WHILE BLOWDRYING CAUSE OF HEAT, NO HEAT GLOVE WHILE FLAT IRONING HOSPITAL 2X, DIZZINESS, SEVERE HEADACHES, DERMATITIS, SINUS PROBLEMS, THROAT NO VOICE, ON AND OFF VOICE, LUNGS TREATED WITH INHALER, NASAL SPRAY, PAIN MEDS, MORPHINE, TAGMETAL, ULTRAM, TESSELOX PEARLES, BREATHING TREATMENTS NO MASK, NO VENTILATION) (MY BOSS OPEN THIS FOR - KEPT BOTTLE LOCKED UP)
✓ 132733	11/20/10	11/22/10	PETER COPOLLA KERATIN STRAIGHTENIN GTREATMENT	UNKNOWN	Ingredient From Label	NA	KERATIN COMPLEX	Corporate Headquarters	MW 3500	From Other Sources	I HAVE HAD 5 COPOLLA KERATIN STRAIGHTENING TREATMENTS OVER A 2 YEAR PERIOD THERE WAS SIGNIFICANT HAIR LOSS WITH ROOT BALL ATTACHED FOR ABOUT 2 MONTHS AFTER EACH TREATMENT THIS HAIR LOSS INCREASED IN VOLUME WITH EACH ADDITIONAL TREATMENT THE LAST TREATMENT DONE IN JULY 2010 CAUSED MASSIVE HAIR LOSS DIAGNOSIS FROM PROMINENT DERMATOLOGIST AT [REDACTED] WAS TELOGEN EFFLUVIUM ADVICE WAS TO STOP KERATIN TREATMENTS AS IT APPEARED TO TRIGGER ABNORMAL INCREASED HAIRS TO GO INTO PREMATURE TELOGEN PART OF CYCLE THIS PRODUCT AS I'M SURE ALL OTHER KERATIN PRODUCTS APPEAR TO CAUSE THIS CONDITION AS MANY OTHER WOMEN HAVE EXPERIENCED EXACT SAME CONDITION RELEVANT TESTS DR [REDACTED] M D FROM [REDACTED] WAS SEEN ON NOVEMBER 18, 2010 FOR EXAMINATION OF HAIR FOLLICLES AND SCALP
✓ 132848	11/25/10	11/29/10	COPPOLA DESIGNER HAIR CARE/KERATIN COMPLEX	UNKNOWN	Ingredient From Label	NA	KERATIN COMPLEX	Corporate Headquarters	MW 3500	From Other Sources	PRESENTING SITUATION APPLICATION OF KERATIN COMPLEX HAIR SMOOTHING TREATMENT IN HAIR SALON NOTE THIS PRODUCT IS SUSPECTED TO CONTAIN FORMALDEHYDE BUT THAT INFORMATION IS NOT REQUIRED TO BE DISCLOSED TO RECIPIENT RESULTS SEVERE NECK RASHES, ITCHING, WELTING, REDNESS, EVENTUALLY ALSO RASH APPEARED ON SIDES OF FACE REDNESS AND SENSITIVITY PERSIST AT THIS TIME -7 DAYS POST EVENT- UPON APPLICATION OF HAIR PRODUCT I EXPERIENCED SEVERE EYE BURNING


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											REACTION, ALSO SLIGHT BLEEDING IN RIGHT NOSTRIL TWO DAYS LATER I AM ALSO QUITE DISTURBED THAT ON-LINE INFORMATION ON THIS PRODUCT IS OF A PROMOTIONAL AND ADVERTISING NATURE--ABSOLUTLEY NO INFORMED, SCIENTIFIC COMMENTARY IS READILY AVAILABLE TO COUNSEL PUBLIC THIS IS DANGEROUS AND I HOPE MORE INFORMATION CAN BE MADE AVAILABLE TO THE PUBLIC AS THIS TREATMENT IS BECOMING INCREASINGLY COMMON I DID NOT REQUEST THIS TREATMENT THE PRACTITIONER ADDED IT BECAUSE HE THOUGHT IT WOULD BE HELPFUL--MUCH TOO INFORMAL USE OF A DANGEROUS CHEMICAL RELEVANT TESTS VISITED DOCTOR ON 11/22/2010, SHE ASKED FOR EVIDENCE OF SURFACE IRRITANTS RECALLING APPLICATION OF HAIR PRODUCT ON PREVIOUS THURSDAY DIAGNOSED ACUTE INFLAMMATORY REACTION UNABLE TO PRESCRIBE HYDROCORTISONE FOR RELIEF AS I HAD TRIED THAT AND IT EXACERBATED ALLERGIC REACTION	
132870	11/02/10	11/02/10	BRAZILIAN BLOWOUT/HAIR STRAIGHTENER	UNKNOWN	Ingredient From Label	PURCHASE DATE 8/2010		Manufacturer	FACTS	Letter/Fax/Ph one	From AE Report	MR [REDACTED] IS THE OWNER AND SOLE OPERATOR OF THE [REDACTED] IN [REDACTED] HE USES BRAZILIAN BLOWOUT TREATMENT ON HIS CLIENTS BY REQUEST THE TREATMENT INVOLVES APPLYING TO DAMP HAIR, BLOWING DRY AND USING A FLAT IRON ON THE HAIR EACH TIME HE HAS USED THIS PRODUCT ON A CLIENT, HE HIMSELF HAS EXPERIENCED BURNING, STINGING EYES AND IMMEDIATELY GETS A HEADACHE AFTER HE FINISHES THE TREATMENT SOME, BUT NOT ALL, OF HIS CLIENTS EXPERIENCE THE SAME SYMPTOMS HE HAS CONTACTED [REDACTED] WHERE HE PURCHASED THE PRODUCT, BUT THEY WERE NOT ABLE TO PROVIDE HIM WITH THE INGREDIENTS IN THE PRODUCT HE BELIEVES THE PRODUCT CONTAINS FORMALDEHYDE, BUT WAS TOLD THAT THE INGREDIENTS ARE PROPRIETARY INFORMATION AND CANNOT BE RELEASED TO THE CONSUMER I ADVISED HIM TO FILL OUT A MEDWATCH FORM COMPLAINT/INJURY REMARKS BURNING, STINGING EYES, HEADACHES FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) HEADACHE / NR / HOUR(S) / NR / IMMEDIATE / NR

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✓ 133106	12/01/10	12/02/10	PURE NV BKT	UNKNOWN	Ingredient From Label	NA	UNKNOWN	Corporate Headquarters	MW 3500	From Other Sources	HAD THE BKT APPLIED TO MY HAIR 8/27/2010, DRASTICALLY CHANGED COLOR OF HAIR IMMEDIATELY AND WITHIN A WEEK HAD EXTREME HAIR LOSS WHICH HAS NOT STOPPED, IT HAS INCREASED BY THE DAY TELOGEN EFFLUVIUM HAIR STILL FALLING OUT 4 MONTHS LATER SICKENED OVER THIS AND WOULD LOVE SOME COMPENSATION FOR THE EXTRA PAIN AND SUFFERING, AND WHO KNOWS WHAT ELSE TO COME!!!! RELEVANT TESTS ALL BLOOD WORK NORMAL 10/20/10 QUEST DIAGNOSTICS OTHER RELEVANT HISTORY SMOKER, OTHERWISE EXCELLENT HEALTH
✓ 133107	12/01/10	12/02/10	BRAZILIAN BLOWOUT ACAI STRAIGHTENER	UNKNOWN	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Manufacturer	MW 3500	From AE Report	I HAD A BRAZILLIAN BLOWOUT AFTER READING THE COMPANY'S LITERATURE THAT IT WAS FORMALDEHYDE FREE WHILE MY STYLIST WAS APPLYING THE SOLUTION TO MY HAIR MY EYES STARTED TO BURN, STING AND TEAR EXCESSIVELY MY EYES REMAINED RED FOR THE REMAINDER OF THE DAY AND I ALSO WAS HAVING PERSISTENT COUGHING FITS
✓ 133134	10/15/10	10/15/10	BRAZILIAN BLOWOUT/SHA MPOO & CONDITIONER	UNKNOWN	Ingredient From Label	NA		Corporate Headquarters	FACTS Letter/Fax/Ph one	From AE Report	COMPLAINANT EXPERIENCED SCALP BURN, RESPIRATORY DISTRESS AFTER HAIRDRESSER USED BRAZILIAN BLOWOUT HER SINUSES, EAR CANAL PAINFUL TWO OTHER CUSTOMERS AT THE SALON WERE ALSO AFFECTED BY STRONG FUMES HER FRIEND,  STYLIST (SEE CC #117544) USED BB ON HER FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) BURNING / 3 / DAY(S) / NR / IMMEDIATE / NR DIFFICULTY BREATHING / 3 / DAY(S) / NR / IMMEDIATE / NR
								Manufacturer	FACTS Letter/Fax/Ph one	From AE Report	
										From Other Sources	I WOULD LIKE FOR THE FDA TO INVESTIGATE FOR UNSAFE LEVELS OF CARCINOGENIC CHEMICALS IN FIBRAZILLIAN BLOWOUTFL DURING AND AFTER APPLICATION IM PARTICULARLY CONCERNED WITH ANY CHEMICAL I COULD CONTINUE TO BE EXPOSED TO IN MY HAIR AFTER THE TREATMENT I CURRENTLY HAVE A PAINFUL SORE THROAT SOME PORTIONS OF MY HAIR WAS APPLIED WITH THE TREATMENT, WHICH TOUCHED MY BARE SKIN -FACE, NECK, AND EARS- I HAD "BRAZILIAN BLOWOUT" TREATMENT PERFORMED

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✓ 133146	12/06/10	12/07/10	BRAZILIAN BLOWOUT	FORMALDEHYDE	Alleged Problem Ingredient not on label	NA	UNKNOWN	Manufacturer	MW 3500		<p>ON MY HAIR TO HAVE LESS FRIZZY HAIR THIS WAS MY FIRST TIME I AM OF ASIAN DESCENT AND HAVE THICK, FRIZZY HAIR THE 2-HOUR PROCEDURE BEGAN AND TERMINATED IN THIS SEQUENCE - HAIR WAS THOROUGHLY WASHED AND TOWEL-DRIED - "BRAZILLIAN BLOWOUT", A CREAM-COLORED SOLUTION IN A SMALL GLASS VIAL WAS EMPTIED IN A PLASTIC BOWL AND APPLIED TO PORTIONS OF MY HAIR WITH A BRUSH AND A COMB, BY A PROFESSIONAL HAIR STYLIST - HAIR STYLIST WORE A SURGICAL FACE MASK AND BLACK INDUSTRIAL GLOVES AND APRON - WITHIN 10 MINUTES OF APPLICATION, MY EYES STUNG SO SEVERELY THAT I WAS TEARING UP - WITHIN 10 MINUTES OF APPLICATION, I FELT A VERY PAINFUL BURNING SENSATION IN MY NOSTRILS - THE SMELL OF THE PRODUCT IS CHEMICALLY PUNGENT AND SWEETLY FRAGRANT - THE NEXT STEP WAS TO BLOW DRY THE HAIR CE THIS TOOK 20 MINUTES THE EYES CONTINUED TO TEAR UP - THE NEXT STEP WAS</p> <p>TO USE A FLAT IRON ON THE HAIR CE THIS TOOK 15 MINUTES THE EYES CONTINUED TO TEAR UP - THE FINAL STEP WAS TO WASH THE HAIR AND APPLY A CONDITIONING TREATMENT THIS TOOK 5 MINUTES THERE WAS NO MORE TEARING UP - MY HAIR WAS BLOW DRIED A FINAL TIME, AND STRAIGHTENED AFTER THE PROCEDURE, I EXPERIENCED THE FOLLOWING - THAT SAME EVENING I HAD A SLIGHT SORE THROAT - THE NEXT MORNING, I HAD A VERY SORE THROAT AND RED EYES THE HAIR STILL HAS THE LINGERING SCENT OF THE APPLICATION FDA, PLEASE HELP TO DETERMINE WHETHER THERE ARE UNSAFE LEVELS OF CHEMICALS AND REGULATE FIBRAZILLIAN BLOWOUTFL RELEVANT TESTS PLEASE TEAT VIALS USED AT [REDACTED] AT [REDACTED] I BELIEVE THE LABELING INDICATES THAT IT IS "FORMALDEHYDE FREE AND ALL NATURAL DUE TO MY SYMPTOMS AND THOSE THAT MY HAIR PROFESSIONAL STYLIST CLAIMED, I REFUTE THIS CONTACT [REDACTED] OTHER RELEVANT HISTORY NO PREEXISTING MEDICAL CONDITIONS I AM OF ASIAN DECENT</p>

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✓ 133195	12/07/10	12/08/10	SIMPLY SMOOTH/KERA TIN BASED SHAMPOO	UNKNOWN	Ingredient From Label	NA	UNKNOWN	Manufacturer	MW 3500	From Other Sources	I STARTED USING A KERATIN BASED SHAMPOO CALLED SIMPLY SMOOTH IN MAY OF 2010 IN MID JULY I NOTICED I BEGAN SHEDDING HAIR AT AN ALARMING RATE I WAS SHAMPOOING WITH THE SHAMPOO ABOUT 4 TIMES PER WEEK I AM CAUCASION WITH WAVY DARK HAIR I WAS USING THIS PRODUCT TO HELP WIT SMOOTHNESS AFTER A BLOW DRY I WOULD SHED UP TO 10 PIECES OF HAIR IN ONE SINGLE LOCATION AFTER RUNNING MY FINGERS THROUGH MY HAIR WHEN I WOULD SHAMPOO, I COUNTED UP TO 100 STRANDS AFTER ONE SHAMPOO, AND THEN MANY MORE DURING STYLING I WAS FEARFUL OF LOSING ALL OF MY HAIR I STOPPED USING THE PRODUCT IN LATE SEPTEMBER WHEN I REALIZED THERE COULD BE AN ASSOCIATION I ABOUT A MONTH AFTER I STOPPED MY HAIR WAS NOT FALLING OUT ANYMORE I HAVE LOST A SIGNIFICANT AMOUNT OF HAIR DUE TO USE OF THIS PRODUCT I HOPE THESE KERATIN PRODUCTS ARE RE-EVALUATED FOR QUALITY AND POSSIBLY TAKEN OFF THE MARKET FOR USE
✓ 133374	12/10/10	12/13/10	BRAZILIAN BLOWOUT TREATMENT	FORMALDEHYDE	Alleged Problem Ingredient not on label	NA	UNKNOWN	Manufacturer	MW 3500	From Other Sources	THE VICTIM IS A PROFESSIONAL HAIR STYLIST WHO WAS INJURED BY HER EXPOSURE TO WHAT ARE COMMONLY REFERRED TO AS THE "BRAZILIAN BLOWOUT" HAIR- STRAIGHTENING PRODUCTS, WHICH WE BELIEVE CONTAIN UNACCEPTABLE LEVELS OF FORMALDEHYDE, WHICH HAVE CAUSED HER TO SUFFER SHORTNESS OF BREATH, FACIAL SWELLING, IRRITATION TO HER EYES, NOSE AND THROAT, THROAT DAMAGE, NASAL DISCHARGE, SPUTUM, SINUS DRAINAGE, COUGHING, INHALATION PNEUMONITIS, BRONCHITIS, HOARSENESS, MEMORY PROBLEMS, AND FATIGUE OTHER RELEVANT HISTORY RELEVANT HISTORY IS THE VICTIM'S EXPOSURE TO HAIR-STRAIGHTENING PRODUCTS IN HER WORK AS A PROFESSIONAL HAIR STYLIST SHE HAS NO OTHER PERTINENT OR CONTRIBUTING HISTORY OR CONDITIONS
											I WENT TO A HAIR SALON TO GET EXTENSIONS AFTER A STYLIST HAD TAKEN THINNING SHEARS DRASTICALLY TO MY HAIR THE STYLIST SAID HE WAS GOING TO PUT A CONDITIONING TREATMENT ON MY HAIR CALLED KERATIN I DID NOT KNOW ABOUT THIS TREATMENT OR I WOULD NOT HAVE PUT THIS ON MY HEAD AS IT HAS HARSH CHEMICALS INCLUDING FORMALDEHYDE IT WAS SEALED IN WITH A HOT IRON WHICH DID BURN MY HAIR,CAUSING FURTHER PROBLEMS THE TREATMENT WAS VERY HEAVY ON MY HAIR CAUSING

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133684	12/13/10	12/14/10	KERATIN EXPRESS	UNKNOWN	Ingredient From Label	NA	KERATIN EXPRESS	Manufacturer	MW 3500	From Other Sources	<p>MY BANGS TO FLATTEN TO MY HEAD AND ABOUT 3 WEEKS LATER MY HAIR STARTED BECOMING VERY BRITTLE AND STARTED BREAKING EXTENSIVELY THE HAIR IN EXTENSIONS WAS PROTECTED AT THE TIME BUT I WAS LOOSING THE EXTENSIONS DUE TO MY BRITTLE HAIR WHEN I HAD THEM TAKEN OUT THE TOP BACK HALF OF MY HAIR WAS THICK BECAUSE IT HAD FINALLY GROWN FROM THE THINNING SHEARS BUT LAY FLAT TO MY HEAD ALMOST IMMEDIATELY THE TOP PART OF MY HAIR BEGAN BREAKING OFF AND FALLING OUT FROM THE ROOT I SAW DERMATOLOGIST AND HE SAID IT WAS THICK AT THE ROOT STILL AND SEEMED AT THAT TIME WAS NOT ANYTHING MEDICAL JUST EXTENSIVE BREAKAGE MY SCALP HAD BEEN ITCHING FROM THE DAY I GOT THE TREATMENT AND HAD BECOME VERY DRY I TRIED ALL SORTS OF DIFFERENT SHAMPOOS, CONDITIONERS ETC BUT MY HAIR CONTINUED TO BREAK AND FALL OUT I WENT BACK TO THE DERMATOLOGIST AND BY THIS</p> <p>TIME MY THICK UPPER HAIR HAD A HUGE BALD SPOT AND I WAS GIVEN STEROID INJECTIONS IT IS DECEMBER NOW AND I HAD TO GO BUY SOME WIGS BECAUSE I DO NOT HAVE MUCH HAIR LEFT MY LAST VISIT TO THE DERMATOLOGIST WAS DISAPPOINTING BECAUSE HE HAD TO TAKE A BIOPSY BECAUSE THE NEW GROWTH IS SPARSE THIN AND GRAY SO MANY SITES AND SO MANY OTHER WOMEN ARE GOING THROUGH THIS HORRIBLE TRAUMA AND THEIR HAIR IS COMING IN THIS AND SPARSE TO MEANING THESE CHEMICALS ARE PENETRATING OUR SCALP AND AFFECTING FURTHER GROWTH THIS IS OUTLAWED IN OTHER COUNTRIES BECAUSE OF THE CHEMICALS IN THESE FORMULAS AND I CAN NOT BELIEVE IT IS NOT BANNED HERE!! I WOULD HAVE THICK HAIR STILL IF NOT FOR THIS PRODUCT AND PRAY I DO NOT GET SICK IN THE FUTURE FROM THESE CHEMICALS AS I HAD A SCARE WHEN MY ANTI NUCLEAR BLOOD WORK CAME BACK POSITIVE FOR POSSIBLE SCLERDOMA WHICH AFFECTS THE SKIN OFTEN RESULTING FROM THE BODY COMBATING A STRANGE CHEMICAL INTRODUCED TO THEIR BODY PLEASE LISTEN TO THE</p> <p>HUNDREDS OF WOMEN WHO ARE LOSING SOMETHING PRECIOUS TO THEM AND HELP BAN THIS PRODUCT! MY KERATIN WAS MADE BY KERATIN EXPRESS RELEVANT TESTS BIOPSY OF SCALP ON 12/11/2010, RESULTS NOT BACK</p>

RA_Report #	RA_Initia l Report Date	SO_FDA Received Date	PRI_Reported Brand/Product Name	PI_One Row Ingredients	PI_Ingrdie nt Category	PRI_Product t Comments	PRM_Firm Name	PRM_Firm Type	SO_Report Format	PRM_Firm Address Type	AEC_Event As Reported
✓ 133841	12/09/10	12/10/10	KERAGREEN ORGANIC KERATIN	UNKNOWN	Ingredient From Label	NA	LORD BEAUTY DESIGNS, INC	Manufacturer	MW 3500	From Other Sources	VICTIM IS A PROFESSIONAL HAIR STYLIST WHO WAS INJURED BY HER EXPOSURE TO WHAT ARE COMMONLY REFERRED TO AS THE 'BRAZILIAN BLOWOUT' HAIR-STRAIGHTENING PRODUCTS, WHICH WE BELIEVE CONTAIN UNACCEPTABLE LEVELS OF FORMALDEHYDE, WHICH HAVE CAUSED HER TO SUFFER SHORTNESS OF BREATH, FACIAL SWELLING, IRRITATION TO HER EYES, NOSE AND THROAT, THROAT DAMAGE, NASAL DISCHARGE, SPUTUM, SINUS DRAINAGE, COUGHING, INHALATION PNEUMONITIS, BRONCHITIS, HOARSENESS, MEMORY PROBLEMS, AND FATIGUE OTHER RELEVANT HISTORY RELEVANT HISTORY IS VICTIMS EXPOSURE TO HAIR-STRAIGHTENING PRODUCTS IN HER WORK AS A PROFESSIONAL HAIR STYLIST SHE HAS NO PERTINENT OR CONTRIBUTING PREEXISTING MEDICAL CONDITIONS
✓ 133968	12/21/10	12/21/10	BRAZILIAN BLOWOUT/PRO FESSIONAL PRODUCTS	UNKNOWN	Ingredient From Label	NA		Corporate Headquarters	FACTS	From AE Report	ON 11/24/2010, MS [REDACTED] CALLED IN TO COMPLAIN ABOUT THE SIDE EFFECTS SHE WAS FEELING FROM THE USE OF BRAZILIAN BLOWOUT IN THE BEAUTY SALON WHERE SHE WORKED IN [REDACTED] MS [REDACTED] SAID SHE HAD USED THE PRODUCT PREVIOUSLY AND EXPERIENCED HEADACHES, BURNING THROAT AND LUNGS, AND NAUSEA SHE COMPLAINED TO THE SALON MANAGER, WHO TOLD HER TO JUST TURN ON THE FAN SHE SAID SHE SINCE HER REACTION TO THE PRODUCT, SHE HAS REFRAINED FROM USING IT, HOWEVER, HER CO-WORKERS USE THE PRODUCT ON A VERY REGULAR BASIS, CAUSING HER TO EXPERIENCE THE SAME REACTIONS OVER AND OVER SHE SAID THE PRODUCT CALLS FOR USE IN A VENTILATED AREA, BUT THAT THE SALON ONLY HAS ONE FAN THAT DOES NOT PROPERLY VENT THE FUMES SHE SAID THAT THE PRODUCT ALSO CALLS FOR USING IT ONLY ONCE WITHIN AN EIGHT-HOUR PERIOD, BUT THAT SHE HAS WITNESSED CO-WORKERS USING IT AT LEAST THREE TIMES WITHIN THAT EIGHT-HOUR PERIOD SHE HAS COMPLAINED TO THE MANAGER SEVERAL TIMES, BUT TO NO AVAIL SHE IS CONCERNED THAT THIS PRODUCT CAUSES MORE HARM THAN GOOD.
									Letter/Fax/Ph one		BECAUSE OF ALL THE SIDE EFFECTS IT CAUSES DURING USE, AND SHE WOULD LIKE TO SEE THIS INVESTIGATED SHE SAID SHE BOUGHT THE PRODUCT ON-LINE AT [REDACTED] BUT SHE COULDN'T PROVIDE A LOT NUMBER OR UPC FOR THE ITEM FACTS SYMPTOM LIST (SYMPTOM/DURATION/DURATION UNITS/ONSET/ONSET UNITS/REMARKS) HEADACHE / NR / NR / NR / NR / NR, NAUSEA / NR / NR / NR / NR / NR, BURNING SENSATION / NR / NR / NR / NR / NR, DIFFICULTY BREATHING / NR / NR / NR / NR / NR

RA_Rep ort #	RA_Initia l Report Date	SO_FDA Received Date	PRI_Reported Brand/Product Name	PI_One Row Ingredients	PI_Ingre dient Category	PRI_Produc t Comments	PRM_Firm Name	PRM_Firm Type	SO_Report Format	PRM_Firm Address Type	AEC_Event As Reported
134420	01/10/11	01/11/11	BRAZILIAN BLOWOUT TREATMENT + SHAMPOO, CONDITIONER, SERUM AND MASQUE	UNKNOWN	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Manufacturer	MW 3500	From AE Report	<p>MY NAME IS [REDACTED] PHONE: [REDACTED] ON AUGUST 29, 2010, I VISITED MY HAIR SALON AND HAD A "BRAZILLIAN BLOWOUT" HAIR TREATMENT. I WASN'T FEELING WELL BUT TRAVELLED TO [REDACTED] ON 9/3. I HAD UPPER RESPIRATORY IRRITATION SYMPTOMS, HEAD COLD OR SO I THOUGHT THAN I BEGAN COUGHING AND WHEEZING WITH CHEAT PAIN. I GOT WORSE IN THE DAYS THAT FOLLOWED AND WENT TO THE [REDACTED] IN [REDACTED] ON 9/8 AND WAS HOSPITALIZED WITH PNEUMONIA. I WAS OUT RECUPERATING FOR THE NEXT SEVERAL WEEKS & UNDER MEDICAL CARE OF MY PRIVATE PHYSICIAN BACK IN [REDACTED]. I STILL HAD CHEST PAIN, WHEEZING, ETC AND ANOTHER MEDICAL CHECK UP REVEALED I HAD FLUID AT THE TOP OF MY HEART MY PHYSICIAN TOLD ME THIS CAN BE A RESULT OF PNEUMONIA. REST, ANTIBIOTICS AND INHALERS HELPED AND WAS BACK ON MY FEET. I WAS IN [REDACTED] EARLY DECEMBER FOR</p> <p>BUSINEAS AND BECAME ILL -GI UPSET, NAUSEA, VOMITING FROM SAM THRU THE NEXT MORNING AT SAM. I FLEW BACK HOME, RESTED AND AM BETTER. ON DEC 14, 2010 SOMEONE COMPLIMENTED ME ON MY HAIR AND I TOLD HIM OF THE BRAZILLIAN HAIR TREATMENT. HE THEN TOLD ME OF THE DANGERS AND HOW FORMALDEHYDE HAS BEEN FOUND IN EXCESS OF PERMISSIBLE LIMITS. [REDACTED] AND [REDACTED] HAS NOW BANNED THE PRODUCT AND I BELIEVE THERE IS LEGAL ACTION IN MOTION. PART OF THE HAIR PROCESS IS TO ALSO USE THE SHAMPOO, CONDITIONER, SERUM AND NIGHT MASQUE SEVERAL NIGHTS A WEEK. I DID SOME RESEARCH TONIGHT AND HAPPENED UPON YOUR WEBSITE I WOULD LIKE TO KNOW DO YOU HAVE ANY INFORMATION ON THIS PRODUCT, DO YOU OR CAN YOU TEST THE PRODUCT TO SEE IF FORMALDEHYDE ALSO EXISTS IN THE PRODUCTS I USE AT HOME? THANK YOU FOR ANY INSIGHT OR INFORMATION YOU MAY OFFER. THANKS</p>
134558	10/13/10	10/14/10	BRAZILIAN BLOWOUT	UNKNOWN	Ingredient From Label	NA	BRAZILIAN BLOWOUT	Corporate Headquarters	MW 3500	From AE Report	<p>REPORTS 131017 AND 134558 ARE RELATED REPORT 131017 IS FOR [REDACTED] REPORT 134558 IS FOR COWORKER. THE BRAZILLIAN BLOW OUT HAS MADE IT HARD FOR TO BREATHE WHILE BLOW DRYING, MY EYES AND MY CLIENTS EYES WATERED AND BURNED MY CO-WORKER BROKE OUT IN HIVES AFTER APPLYING RELEVANT TESTS / LABORATORY DATA, INCLUDING DATES REMARKS. [REDACTED] HAS REVIEWED THAT IT HAS CONTAINED 10% FORMALDEHYDE.</p>
50											

United States Food and Drug Administration

Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 10/14/2010

COMPLAINT # 117127

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
10/08/2010	DEN-DO	LOS-DO	Telephone	Consumer	Chastagner,Steph anie C	Pending at Branch

Complainant Identification

Name

Address

Phone (W)

Phone (H)

Source POC Name

Source Phone

SAA

Complaint/Injury

Complaint Description

**Adverse Event
Result**

**Adverse Event
Date**

Injury / Illness

On October 8, 2010 [REDACTED] had her hair straitened using the Brazilian Blowout procedure/product. [REDACTED] and her hair dresser [REDACTED] both had a sever reaction to the product. Both had burning eyes, burning nose, sore/raw throat and acute headache. This is the first exposure either of them has had to the Brazilian Blowout product. Neither woman had any known allergies. The product claims that it contains NO formaldehyde. The label has no lot numbers, no best by date, no ingredient list and no country of origin information. The MSDS for this product dose not list ANY chemical agents however Brazilian Blowout confirms by phone and on there website that the product contains Methylene Glycol. Methanediol, also known as formaldehyde monohydrate or methylene glycol, is a chemical compound with chemical formula CH4O2, or H2C(OH)2. It is the simplest geminal diol, and formally the second simplest carbohydrate new to Formaldehyde. Brazilian Blowout has posted that OSHA's testing methods prove faulty. Please see: <http://www.brazilianblowout.com/pdf/october08.pdf>

Non-Life
Threatening
Injury/Illness

10/07/10

Severe
Respiratory
Distress
Syndrome/Bronc
ho-constriction
or bronchospasm

Health Canada has issued The following warning "Health Canada is warning Canadians that Brazilian Blowout Solution manufactured by Brazilian Blowout of California has been found to contain unacceptable levels of formaldehyde." And "Testing conducted by Health Canada found that the Brazilian Blowout Solution contains 12% formaldehyde. Formaldehyde is permitted in cosmetics at less than 0.2% when used as a preservative. Formaldehyde is a known irritant, sensitizer, and is linked to cancer in humans when inhaled chronically over a long period of time. Health Canada believes that the reactions are being caused by formaldehyde becoming aerosolized during the blow drying and flat ironing stages of the treatment. Any procedure containing formaldehyde above the allowable limits places clients and stylists at increased risk."

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	10/14/2010	No	No	No	Unknown	

Remarks

The entire letter can be seen at http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2010/2010_167-eng.php Ms. Tonni Ratcliff the Manager for Brazilian Blowout stated that the "Federal" FDA had cleared there product as safe. On review of Brazilian Blowout in FACTS it appears that FDA has not contacted Brazilian Blowout the Manufacturer/United States distributor of this product. This product is manufactured in Brazil.

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Burning	SKIN	Immediate	Hours	
Choking	RESPIRATORY	Immediate	Hours	

Health Care Professional

Provider Name	Address	Phone	Occupation
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Hospital Information

Hospital Name	Address	Phone	Dates of Stay
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Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
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Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Brazilian Blowout	Brazilian Blowout	53YD-99	Other Cosmetic and Cosmetic Products, N.E.C.; Liquid, Lotion	29R801	None

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used Yes	Amount Consumed/Used 1 use
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Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
10/07/10	10/07/10		Yes	Brazil	Contains no Formaldehyde. Not tested on Animal

Retail

Name	Address
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Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3008415878	Brazilian Blowout 6867 Farmdale Ave North Hollywood California United States 91605-6209	LOS-DO	Corporate Headquarters
3008415884	Brazilian Blowout 6867 Farmdale Ave N Hollywoodn Hollywood California United States 91605	LOS-DO	Importer
3008575862	Brazilian Blowout 10615 W Vanowen St Burbank California United States 91505-1136	LOS-DO	Distributor

Initial Evaluation/Initial Disposition**Problem Keyword**

Reaction

Problem Keyword Details

burning eyes, burning nose, sore/raw throat and acute headache

Initial Evaluation

FDA Action Indicated

Initial Disposition

Referred to Other FDA District

Disposition Made By

Chastagner,Stephanie C

Disposition Date

10/14/2010

Initial Disposition Remarks**Referrals****Org Name**

OEO

LOS-IB-CCC

HHS Mail Code

HFC-160

HFR-PA250T

There are no Adverse Event details for this Complaint.

COSMETICS	Product Name Brazilian Blowout	Product Code 53YD-99
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Birth Date	Age	Gender Female	Race	Application Place Salon/SPA	Reason for Use Hair Preparations (Non-Coloring)
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Body Application Site Hair	Reaction Site Other, identify in Remarks
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Were Other Products Used on same Site? N/A	Other Products Used	Last Time Product Used
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Directions	Were Directions Followed?	Was Product Used in 'Off Label' Manner?	Product Used 'Off Label' Manner Description
Wash Hair/ Put solution on hair/ Blowout hair with hair dryer/ Blow dry hair/ Wash hair/ Style	Yes	No	

Warning Statements on Label? No	Warning Statements	How Long Product Used? First Use	How Frequent Product Used? Other
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Any Preexisting Conditions? No	Total Duration Time Hours	Treatment? Self-medicated	Current Status Improved
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Medical Diagnosis	Medical Treatment
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Remarks

Burning eyes, burning nose, sore/raw throat and acute headache

United States Food and Drug Administration
Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 10/20/2010

COMPLAINT # 117159

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
10/18/2010	CIN-DO	FLA-DO	Telephone	Consumer	Paulin, Nicholas L	Pending at Branch

Complainant Identification

Name **Address**

[REDACTED]

[REDACTED]

Phone (W) **Phone (H)** **Source POC Name** **Source Phone**

[REDACTED]

Complaint/Injury

Complaint Description

Adverse Event Result

Adverse Event Date

Injury / Illness

[REDACTED] stated that she is a hair stylist at [REDACTED]. She's around other hair stylist that applies this product (Coppola Keratin Complex Smoothing Therapy) to customers scalps 2-3 times daily. She claims that this product is being used by all of the other hair stylists at the salon. She mentioned that this product started to be used in their salon in May 2010. She states that this product when applied to customers hair by other hair stylist in the salon she becomes nauseous, dizzy, gets a sore throat, has a racing heart, double vision, eyes burn, gets a tightness in her chest, headache, fever and has a lack of oxygen to the brain.

Non-Life
Threatening
Injury/Illness

She mentioned that when she is in the same area as other hair stylist applying this product to a customer's hair, the fumes are intense. The hair stylist will heat up the flat iron to approximately 450 degrees while this product is on the scalp. She claims that this heat and the product combine to releases a gas into the air which causes her numerous side effects. She stated that her salon that she works in is approximately 4000 sq. ft. and gets smoky when this product is applied to customers hair by the entire hair salon staff on a daily basis.

She went to her doctor on 6/23/10 and he stated that according to her symptoms she is being over exposed to fumes and that there isn't anything he could do for her. The doctor stated that she should be wearing a gas mask around a product causing this much side effects. [REDACTED] stated that it took around 2 weeks to get through all the symptoms after first being exposed to these fumes from the product.

The owner of the salon does not require employees to use the product. Only the hair stylist that wants to use the product has that choice. The price for one hair treatment ranges from approximately \$300 - 400 per scalp.

Other co-workers that apply the product to customers hair are also having side-effects such as anxiety and inflamed hands.

Date: 10/20/2010

Page: 1 of 5

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	10/18/2010	Yes	No	No	Not Report to Other Source	No

Remarks

Note: Please keep patient confidential. She mentioned that she does not want her boss/salon to find out that she contacted FDA regarding this issue.

██████████ stated that she has never applied this hair product to anybody's scalp. She chooses not to use this product.

This complaint is to be forwarded up to CFSAN.

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Dizziness or problems with balance	NERVOUS	Immediate	1 Weeks	
Headache	CARDIOVASCULAR	1 Hours	2 Days	
Change in vision	NERVOUS	1/2 Hours	2 Weeks	Double vision
Dizziness or problems with balance	NERVOUS	Immediate	1 Days	
Sore throat	RESPIRATORY	2 Hours	1 Months	
NEC - Identify in Remarks	NEC	1 Days	2 Days	Fever
NEC - Identify in Remarks	NEC	Immediate	1 Weeks	Tightness of Chest
Nausea	GASTROINTESTINAL	Immediate	1 Days	

Health Care Professional

Provider Name	Address	Phone	Occupation
██████████	██████████	██████████	██████████

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Coppola	Keratin Complex Smoothing Therapy	53ED-03	Hair Straighteners (Hair Preparations, Non-coloring); Liquid, Lotion	29R801	N/A

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
32 Ounces Bottle	072210 Batch Code: 0048KT	None	May 2010	No	N/A

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
May 2010 to present	N/A		No		

RetailProblem Ingredient Group

Name	Address
[REDACTED]	[REDACTED]

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3006524310	Copomon Enterprises, LLC 7700 Congress Ave Ste 2201 Boca Raton Florida United States 33487-1361	FLA-DO	Manufacturer

Initial Evaluation/Initial DispositionProblem KeywordProblem Keyword Details

Reaction

Dizziness, eyes burning, headache, double vision, heart racing, sore throatat

Initial EvaluationInitial DispositionDisposition Made ByDisposition Date

FDA Action Indicated

Referred to Other FDA District

Paulin,Nicholas L

10/19/2010

Initial Disposition RemarksReferralsOrg NameHHS Mail Code

FLA-IB

HFR-SE250

There are no Adverse Event details for this Complaint.

COSMETICS	Product Name Keratin Complex Smoothing Therapy	Product Code 53ED-03
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Birth Date [REDACTED]	Age [REDACTED]	Gender Female	Race White	Application Place Salon/SPA	Reason for Use Hair Preparations (Non-Coloring)
Body Application Site Scalp		Reaction Site Other, identify in Remarks			
Were Other Products Used on same Site? No		Other Products Used		Last Time Product Used	
Directions Apply from root to end. Make sure the hair is saturated. Client sits for 20 minutes as processing it on scalp. Then blow dry hair. Flat iron with 450 degrees (activates the gas being released into the air). States that it lasts up to 4 months.		Were Directions Followed? Yes		Was Product Used in 'Off Label' Manner? Unknown	
Warning Statements on Label? Unknown		Warning Statements None		Product Used 'Off Label' Manner Description Product is only used for the hair straintening	
How Long Product Used? Months		How Frequent Product Used? Other			
Any Preexisting Conditions? No		Total Duration Time Persists		Treatment? Physician	
				Current Status Worsening	

Medical Diagnosis

[REDACTED] stated that hair stylist needs to be using gas mask. He stated long term effect can cause lung cancer, nose cancer, throat cancer, asthma, emphysema, bronchitis

Medical Treatment**Remarks**

The complainant is not the user - the complainant is the hair stylist that is in the same proximity of the product. She is claiming that the product makes her dizzy and nauseous. She states this product is being used in the salon daily (2-3x per hair stylist).

COMPLAINTS FOLLOW - UP**Grouped Follow - Up Operations**

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
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There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
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Follow-Up Disposition	Disposition Made By	Disposition Date
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Disposition Remarks**Follow-Up Sent To**

Organization Name	HHS Mail Code
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United States Food and Drug Administration
Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 10/20/2010

COMPLAINT # 117188

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
10/19/2010	NWJ-DO	NWJ-DO	Telephone	Consumer	Seland, Virginia	In Progress - Pending Evaluation

Complainant Identification

Name

Address

Phone (W)

Phone (H)

Source POC Name

Source Phone

Complaint/Injury

Complaint Description

Adverse Event Result

Adverse Event Date

Injury / Illness

_____ is a hairstylist in _____. As part of her job, she applies Coppola Keritin Treatment to her clients' hair, as well as Coppola Express Blowout. Whenever she applies this treatment to her clients hair or whenever it is being applied to other hairstylists clients, _____ experiences heart palpitations, lightheadedness, and burning in her eyes, nose and throat. The symptoms are most pronounced when she herself applies the product; however, she experiences some degree of symptoms whenever these products are being used in the salon. She is most sensitive to the Coppola Keritin Treatment. She has been to her _____ and has been diagnosed with severe respiratory allergic reaction.

Non-Life
Threatening
Injury/Illness

Severe
Respiratory
Distress
Syndrome/Bronc
ho-constriction
or bronchospasm

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	10/19/2010	Yes	No	No	Not Report to Other Source	No

Remarks

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Dizziness or problems with balance	NERVOUS	Immediate	Persists	
Eye irritation	NERVOUS	Immediate	Persists	

Health Care Professional

Provider Name

Address

Phone

Occupation

Date: 10/20/2010

Page: 1 of 4

Hospital Information

Hospital Name	Address	Phone	Dates of Stay
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Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
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Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Coppola	Keritin Treatment & Express Blowout	53EC-01	Hair Conditioners (Hair Preparations, Non-coloring); Cream	29R801	

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used No	Amount Consumed/Used
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Date Used	Date Discontinued	Amount Remained	Imported Product? No	Country of Origin	Label Remarks
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RetailProblem Ingredient Group

Name	Address
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Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
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Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
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Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
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Initial Disposition Remarks

Referrals

Org Name	HHS Mail Code
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There are no Adverse Event details for this Complaint.

COSMETICS	Product Name Keritin Treatment & Express Blowout	Product Code 53EC-01
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Birth Date	Age	Gender Female	Race	Application Place Salon/SPA	Reason for Use Hair Preparations (Non-Coloring)
Body Application Site Hair		Reaction Site Other, identify in Remarks			
Were Other Products Used on same Site? Unknown		Other Products Used	Last Time Product Used		
Directions	Were Directions Followed? Yes	Was Product Used in 'Off Label' Manner? No	Product Used 'Off Label' Manner Description		
Warning Statements on Label? Unknown	Warning Statements	How Long Product Used? Years	How Frequent Product Used? Other		
Any Preexisting Conditions? Unknown	Total Duration Time Days	Treatment? Physician	Current Status Unchanged		
Medical Diagnosis Severe respiratory allergic reaction		Medical Treatment			

Remarks

complainant is a hairstylist and is regularly exposed to product; lightheadedness, heart palpitations, burning of eyes, nose and throat

COMPLAINTS FOLLOW - UP**Grouped Follow - Up Operations**

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
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There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
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Follow-Up Disposition	Disposition Made By	Disposition Date
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Disposition Remarks**Follow-Up Sent To**

Organization Name	HHS Mail Code
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**United States Food and Drug Administration
Consumer Complaint / Injury Report**

This is an accurate reproduction of the original electronic record as of 10/29/2010

COMPLAINT # 117280

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
10/21/2010	LOS-DO	LOS-DO	Telephone	Consumer	Lee, Franklin	In Progress - Pending Evaluation

Complainant Identification

Name **Address**

[REDACTED]

[REDACTED]

Phone (W) **Phone (H)** **Source POC Name** **Source Phone**

[REDACTED]

Complaint/Injury

Complaint Description

Adverse Event Result

Adverse Event Date

Injury / Illness

Complainant [REDACTED] female incurred severe neuro and physical reaction from using Brazilian Blowout ("BB") at local salon. Complainant recovered from brain surgery 7 years ago following physical assault incident that left her speech, stability, cognitive abilities compromised. She has been successfully managing her disabilities until after this hair treatment. Complainant went to [REDACTED] on 9/22/10. Brazilian Blowout was used as well as another BB product applied at end of session. Complainant was told to not remove product for 8 days until she return to the salon. After 2-3 days chemical odor and scalp pain became so unbearable she had to rinse her hair. Shortly thereafter, flu-like symptoms emerged, including headaches, vomiting and her stability problem re-emerged. Clusters of her hair were also falling off. Complainant contacted salon owners to obtain BB ingredients but was denied. Complainant's condition continued to deteriorate -- persistent vomiting, difficulty breathing, chest, eye and nose irritation developed.

Non-Life
Threatening
Injury/Illness

9/25/10

Anaphylactic or
Hypotensive
Episodes

10/1/10, Complainant went to [REDACTED] Physician dx her with severe head swelling, hives. Rx antibiotic and steroids. Complainant also has COPD and controlled asthma which chemical odor re-inflamed. On 10/2/10 Complainant went back to salon to secure more ingredient information about BB but salon owner, the attending hairdresser denied wrongdoing and refused to assist her. 10/20/10, Complainant was admitted to [REDACTED] for respiratory distress (compromising her ability to speak), severe stability problems, persistent vomiting (6-7x/day). She had lost significant body weight and req'd IV input to restablize her condition. Physician called poison control and was told that BB did not contain any "harmful" chemicals; however, Canada has impose an embargo on the product. 10/10/10, Oregon issued statement re presence of formaldehyde.

(See Remarks)

Date: 10/29/2010

Page: 1 of 5

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	10/22/2010	Yes		Yes		

Remarks

(Cont Complaint Description)

Complainant scheduled apptmt with her neurologist and physician from [REDACTED] who first attended to her reactive condition with BB products.

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Burning	SKIN	3 Days	5 Days	scalp burning, itching
Change in body weight	METABOLIC	3 Weeks	Persists	lost weight due to inability to hold food down
Change in sensation (numbness, tingling)	NERVOUS			
Difficulty breathing	RESPIRATORY	3 Days	Persists	respiratory impairment
Hair breakage	SKIN	5 Days	1 Months	clumps of hair falling off scalp
Hives (urticaria, welts)	SKIN	3 Days	3 Weeks	Urgent Care dx hives
Local swelling	BLOOD OR LYMPHATIC	3 Days	Weeks	Head swollen
Nausea	GASTROINTESTINAL	1 Days	4 Weeks	
Dizziness or problems with balance	NERVOUS	3 Days	Persists	
Vomiting	GASTROINTESTINAL	3 Days	4 Weeks	off/on episodes

Health Care Professional

Provider Name
could not recall

Address

Phone

Occupation

Hospital Information

Hospital Name

Address

Phone

Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name

Address

Phone

ER Date

10/20/10

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Brazilian Blowout	Hair Straightener	53ED-01	Hair Conditioners (Hair Preparations, Non-coloring); Liquid, Lotion	29R801	

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
				Yes	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
9/22/10	9/22/10		No		Product professionally applied

RetailProblem Ingredient GroupNameAddressManufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3008575862	Brazilian Blowout 10615 W Vanowen St Burbank California United States 91505-1136	LOS-DO	Importer

Initial Evaluation/Initial DispositionProblem KeywordProblem Keyword Details

Chemical

presence of unauthorz chemical

Potency

product too strong

Reaction

Severe physical reaction

Initial EvaluationInitial DispositionDisposition Made ByDisposition Date

FDA Action Indicated

Immediate Follow-Up

Lee, Franklin

10/22/2010

Initial Disposition Remarks

Numerous complaints pertaining to Brazilian Blowout

ReferralsOrg NameHHS Mail Code

LOS-DO

HFR-PA200

There are no Adverse Event details for this Complaint.

COSMETICS	Product Name Hair Straightener	Product Code 53ED-01
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Birth Date	Age ●	Gender Female	Race Question Not Asked	Application Place Salon/SPA	Reason for Use Hair Preparations (Non- Coloring)
Body Application Site Hair	Reaction Site Scalp				
Were Other Products Used on same Site?	Other Products Used	Last Time Product Used			
Unknown	Other product used unspecified by salon operator	9/22/10			
Directions	Were Directions Followed?	Was Product Used in 'Off Label' Manner?	Product Used 'Off Label' Manner Description		
	Unknown	Unknown			
Warning Statements on Label?	Warning Statements	How Long Product Used?	How Frequent Product Used?		
Unknown		First Use	Other		
Any Preexisting Conditions? Yes	Total Duration Time	Treatment?	Current Status Worsening		
Medical Diagnosis	Medical Treatment				

Remarks

Complainant has physical and neurological disabilities from post-trauma event seven years ago.

COMPLAINTS FOLLOW - UP**Grouped Follow - Up Operations**

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
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There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
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Follow-Up Disposition	Disposition Made By	Disposition Date
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Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code
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COMPLAINTS FOLLOW - UP**Grouped Follow - Up Operations**

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
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There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
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Follow-Up Disposition	Disposition Made By	Disposition Date
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Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code
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United States Food and Drug Administration**Consumer Complaint / Injury Report**

This is an accurate reproduction of the original electronic record as of 02/08/2011

COMPLAINT | # **117387**

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
10/28/2010	LOS-DO	LOS-DO	Telephone	Consumer	Lee, Franklin	In Progress - Pending Evaluation

Complainant Identification

Name	Address
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(b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
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(b) (6)

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
On 9/11/10, Complainant (31 y/o female), manicurist at (b) (4), developed headache, nausea, fatigue and anxiety symptoms whenever Brazilian Blowout used at the salon. She confided this to her stylist/friend at the salon and discovered that she too had same reaction. Also, her friend's long time (7 yrs) customer, (64 y/o female), an asthmatic, never used an inhaler, but became severely ill when she came to salon when Brazilian Blowout was used. After short exposure to product odor, the customer was forced to use the device. She now suffers with severe respiratory impairment. This customer's reaction corresponded whenever BB is being used.	Non-Life Threatening Injury/Illness		Severe Respiratory Distress Syndrome/Broncho-constriction or bronchospasm

Complainant is very concerned that when she is exposed again, she will incur more severe health problems. According to Complainant, the salon owner is going to permit use of BB in spite of potential harmful effects.

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	11/02/2010				Not Report to Other Source	

Remarks

Complaint reported to salon owner

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Headache	CARDIOVASCULAR	3 Hours	1 Days	onset at home after exposure at salon
Nausea	GASTROINTESTINAL	4 Hours	1 Days	duration same as headache
Fatigue, weakness	MUSCULO-SKELETAL	4 Hours	4 Weeks	
Difficulty breathing	RESPIRATORY	4 Hours	4 Weeks	

Health Care Professional

Provider Name	Address	Phone	Occupation
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Hospital Information

Hospital Name	Address	Phone	Dates of Stay
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Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
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Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Brazilian Blowout	hair conditioner	53ED-03	Hair Straighteners (Hair Preparations, Non-coloring);Liquid, Lotion	29R801	

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
				No	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
			No		

Retail**Problem Ingredient Group**

Name	Address
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(b) (4)

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3008575862	Brazilian Blowout 10615 W Vanowen St United States 91505-1136	Burbank California LOS-DO	Warehouse- Ambient Storage

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	respiratory impairment exposure to hair care product

Initial Evaluation

FDA Action Indicated

Initial Disposition

Immediate Follow-Up

Disposition Made By

Lee, Franklin

Disposition Date

11/02/2010

Initial Disposition Remarks

This CC is OSHA and EPA applicable.

Referrals**Org Name**

LOS-DO

HHS Mail Code

HFR-PA200

There are no Adverse Event details for this Complaint.

COSMETICS	Product Name	hair conditioner	Product Code	53ED-03
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Birth Date	Age	Gender	Race	Application Place	Reason for Use
	31	Female	Question Not Asked	Salon/SPA	Hair Preparations (Non- Coloring)
Body Application Site	Reaction Site				
Hair	Chest				
Were Other Products Used on same Site?	Other Products Used	Last Time Product Used			
Yes, identify in Other Products Used	Brazilian Blowout Conditioner				
Directions	Were Directions Followed?	Was Product Used in 'Off Label' Manner?	Product Used 'Off Label' Manner Description		
	Unknown	N/A			
Warning Statements on Label?	Warning Statements	How Long Product Used?	How Frequent Product Used?		
Unknown					
Any Preexisting Conditions?	Total Duration Time	Treatment?	Current Status		
No					
Medical Diagnosis	Medical Treatment				
Remarks					
strong chemical odor resembling presence of formalahyde					

COMPLAINTS FOLLOW - UP**Grouped Follow - Up Operations**

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
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There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
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Follow-Up Disposition	Disposition Made By	Disposition Date
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Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code
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United States Food and Drug Administration**Consumer Complaint / Injury Report**

This is an accurate reproduction of the original electronic record as of 02/08/2011

COMPLAINT | # **117544**

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
10/15/2010	LOS-DO	LOS-DO	Telephone	Consumer	Lee, Franklin	Follow Up Requested

Complainant Identification

Name	Address
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(b) (6)

Phone (W)

Phone (H)

Source POC Name

Source Phone

(b) (6)

Complaint/Injury**Complaint Description****Adverse Event
Result****Adverse Event
Date****Injury / Illness**

Complainant (female, 42 y.o) hairstylist @ (b) (4) experienced instant burn in eye, sinus and ear canal congestion upon initial exposure to Brazilian Blowout hair care product. At time of this complaint, Complainant had presence of blood whenever nose is blown. Subsequent exposure to (4X) the product created respiratory distress to extent that she cannot take deep breaths. Complainant was seen by ophthalmologist @ (b) (6) and dx symptoms including blepharitis, (chronic inflammation of eyelids caused by backup in meibomian gland). Posterior side of eye.

Non-Life
Threatening
Injury/Illness

~ 9/2010

Other - identify
in Remarks

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	11/05/2010	Yes				Yes

Remarks

Severe irritation of eyes and respiratory system. Possible presence of formaldehyde in products

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Burning	SKIN	Immediate	1 Days	
Difficulty breathing	RESPIRATORY	Immediate	Persists	
Eye irritation	NERVOUS	Immediate	3 Days	
Other Blood and Lymphatic	BLOOD OR LYMPHATIC	2 Hours	2 Minutes	nose bleed; intermittent

Health Care Professional

Provider Name

Address

Phone

Occupation

(b) (6)

Optometrist

Hospital Information

Hospital Name

Address

Phone

Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
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Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Brazilian Blowout	Hair straightening & conditioner	53ED-03	Hair Straighteners (Hair Preparations, Non-coloring);Liquid, Lotion	29R801	

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
				No	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
			Yes	Brazil	

RetailProblem Ingredient Group

Name	Address
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(b) (4)

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
3007129680	Cadiveu Cosméticos Martim De Sa 75 Sao Paulo Brazil		Manufacturer
3008575862	Brazilian Blowout 10615 W Vanowen St Burbank California United States 91505-1136	LOS-DO	Warehouse-Ambient Storage
3008593985	Brazilian Blowout 6855 Tujunga Ave North Hollywood California United States 91605-6312	LOS-DO	Corporate Headquarters

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	respiratory impairment
Off-Odor	strong chemical odor
Chemical	possible presence of formaldehyde

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Immediate Follow-Up	Lee, Franklin	11/05/2010

Initial Disposition Remarks

BB Corp ct: Mike Brady, CEO. 877.779.7706 x2141. Mfg is OAS, but active ct: anteo@cadiveu.com

Referrals

Org Name	HHS Mail Code
LOS-DO	HFR-PA200

There are no Adverse Event details for this Complaint.

COSMETICS	Product Name Hair straightening & conditioner	Product Code 53ED-03
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Birth Date	Age	Gender	Race	Application Place	Reason for Use
	42	Female	Question Not Asked	Salon/SPA	Hair Preparations (Non- Coloring)
Body Application Site	Reaction Site				
Hair	Chest				
Were Other Products Used on same Site?	Other Products Used	Last Time Product Used			
Unknown					
Directions	Were Directions Followed?	Was Product Used in 'Off Label' Manner?	Product Used 'Off Label' Manner Description		
	Unknown	Unknown			
Warning Statements on Label?	Warning Statements	How Long Product Used?	How Frequent Product Used?		
Any Preexisting Conditions?	Total Duration Time	Treatment?	Current Status		
			Improved		
Medical Diagnosis		Medical Treatment			

Remarks

Complainant did not use product; instead, was present when product was used by other stylists in the salon

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
5115331	31	1234283	LOS-DO	LOS-IB-RY	657709		Completed	12/17/2010
5115328	13	1234283	LOS-DO	LOS-IB-RY			Awaiting Endorsement	12/14/2010
5115331	31	1234283	LOS-DO	LOS-IB-RY	657709		Completed	12/17/2010
5115331	31	1234283	LOS-DO	LOS-IB-RY	657709		Completed	12/17/2010
5115331	31	1234283	LOS-DO	LOS-IB-RY	657709		Completed	12/17/2010
5115331	31	1234283	LOS-DO	LOS-IB-RY	657709		Completed	12/17/2010
5115331	31	1234283	LOS-DO	LOS-IB-RY	657709		Completed	12/17/2010
5115331	31	1234283	LOS-DO	LOS-IB-RY	657709		Completed	12/17/2010

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
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Follow-Up Disposition	Disposition Made By	Disposition Date
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Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code
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