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SUMMARY

This comprehensive inspection of B&R Products Inc., a wholesale cosmetic manufacturer, located at 18721 SW 104th Ave. Miami, FL 33157 was initiated in response to a request made by the CFSAN Office of Cosmetics and Colors (OCAC) due to a high number of Adverse Events Reports filed for (b) (4) brand cosmetic products, which are manufactured under contract by B&R Products Inc. The assignment was performed under eNspect Operation ID# 91963 FY 18 Cosmetic Inspection and conducted in accordance with CP7329.001 Cosmetics Program; Import and Domestic.

B&R Products Inc. has a variety of hair care products including but not limited to: shampoos, conditioners, hair creams, hairsprays, and children hair care products. (b) (4) web pages and promotional material for some of (b) (4) products bear claims of increasing the hair growth and collagen, and reducing DHT hormone, and as such, may be considered both, cosmetics and over the counter (OTC) drugs.

The previous inspection was conducted on 08/16/2010 by the Food and Drug Administration with a classification of NAI, and no objectionable conditions noted.

The current inspection covered the following areas: cGMPs, including manufacturing, quality control and cleaning/sanitizing operations; record review; and consumer complaints. Records reviewed included: bills of lading, packing lists, invoices, batch records, pest control records, complaint records, lab test records, and microbiological preservative challenge studies. Additional records collected during inspection are the product information files (PIFs) and hair damage testing. The following observations were noted and issued to the firm on a Form FDA 483:

- A reactor was observed with an open lid while in-process product was contained in it
- Old product residues were observed in a clean and sanitized reactor
- Hoses were stored without protective caps after cleaning and sanitization was performed
- Personal item was stored next to a filling line, and
- Empty containers were left uncovered in the filling line after production day ended.

The firm committed to implement corrective actions for these observations.

The firm has not registered with the FDA's Voluntary Cosmetic Registration Program or the Cosmetic Product Ingredient Statement. Under the cosmetic regulation, the firm is not required to provide copies of the batch records and firm did not provided these copies even when copies of batch records were provided during the previous inspection. Samples of (b) (4) products were collected per OCAC request during the inspection.

I provided and discussed the following documents with the firm: Guidance for Industry: Cosmetics Processors and Transporters of Cosmetics Security Preventive Measures Guidance and Attachment E: Facts sheet for Cosmetic Manufacturers, Packers and Distributors fact sheet.

Mrs. Castellon was advised about his firm's responsibility to adhere to requirements of the FD&C Act, and that legal sanctions including seizure, injunction, civil monetary penalties and prosecution are available to FDA if establishments do not voluntarily correct serious deviations.

ADMINISTRATIVE DATA

Inspected firm:	B and R Products, Inc.
Location:	18721 SW 104th Ave Cutler Bay, FL 33157-6832
Phone:	305-238-1592
FAX:	(305)378-8528
Mailing address:	PO Box 970671 Miami, FL 33197-0671
Dates of inspection:	3/12/2018-3/14/2018, 3/16/2018, 3/19/2018-3/20/2018

Days in the facility: 6
Participants: **Marinee Flores-Marrero, Investigator**
Goran Periz, FDA Center Employee or Employee of Other Federal Agencies

On 03/12/2018, upon arrival at the firm Mr. Goran Periz, Staff fellow from OCAC and I, CSO Marinée Flores-Marrero, identified ourselves and presented our credentials to Mrs. Joanne Dillon, who identified herself as the director of Quality Control/Assurance (QC/QA), and the most responsible person at that moment in the firm. After showing our credentials to her, we issued Mrs. Dillon a form FDA 482, "Notice of Inspection", dated 03/12/2018 (**Attachment #2**). I was told that Mrs. Maria Castellon, president of B&R Products, Inc. was not in the firm.

I did not encounter representatives from other federal, state or local government agencies during the inspection. The firm is registered with the Florida Department of Business and Professional Regulation Division of Drugs, Devices and Cosmetics who also have the authority to conduct inspections to them.

On 03/20/2018, at the conclusion of the inspection, an FDA-483, Inspectional Observations (**Attachment #1**), was issued to Mrs. Maria Castellon, President of B&R Products Inc. During the close out meeting, 483 items were discussed with Mrs. Castellon, Mrs. Joanne Dillon (Director QC/QA), and Mr. Jamie Ross (Senior Vice President and Technical Services & Manufacturing). A FDA Form 363a affidavit was issued to Mrs. Castellon, but as per instructions from the firm's attorney, she did not sign any document. Mrs. Castellon added a note at the end of the affidavit stating this and initialed it. Form FDA 484, Receipt for Sample was also issued to Mrs. Castellon but again, she refused to sign it; however, the firm proposed that could Mrs. Dillon sign the form since she was present during the sample collection. I notified FDA Division management of the request and was instructed to cross out Mrs. Castellon's name on the FDA 484 and add Mrs. Dillon to it as affiant. During the close out meeting I provided to the firm: Cosmetics Processors and Transporters of Cosmetics Security Preventive Measures Guidance; and Attachment E: Facts sheet for Cosmetic Manufacturers, Packers and Distributors fact sheet.

A new form FDA 482 was issued on 04/02/2018 as an amendment to the form FDA 483 issued on 03/20/2018, due to incorrect dates in the text, noticed after the closeout meeting. A technical error in the eNspect Field Client caused multiple FDA 483 amendments to be generated; however, all FDA 483 amendments in the system are identical.

Mrs. Castellón and Mrs. Dillon promised voluntary corrected actions and a written response to the division director of HAFE4 detailing the extent of corrective actions. The firm has not registered its manufacturing establishment or its cosmetic product formulation with the FDA.

Mrs. Castellon provided administrative information about the firm when requested. She was present at the

closing meeting and she is present on a regular basis at the firm.

Mr. Goran Periz was present at the firm during the following dates: 03/12/2018, 03/13/2018, and 03/14/2018. CSO Aaron Coleman participated in the sample collection performed on 03/19/2018.

This report was prepared and written in its entirety by Investigator Marinée Flores-Marrero.

HISTORY

The information in this section was mainly provided by Mrs. Maria Castellon, president of B&R Products Inc. and Mrs. Joanne Dillon, director of QC/QA.

B&R Products Inc. is a Florida Profit Corporation that manufactures cosmetics (mainly hair care products). The firm is the contracted manufacturer for (b) (4)

The legal name of the firm is B&R Products Inc. (also referred in this report as the "firm"). The firm was incorporated in the state of Florida in November 1977. The parent company is Alcora Corporation and includes B&R Products Inc. as well as (b) (4) . Alcora Corp. and (b) (4) have the same address: 3470 NW 82nd Ave. Suite 910 Miami, FL 33122.

According to Florida Department of State, Division of Corporations, (www.sunbiz.org), Mr. Rayner Urdaneta is listed as President Senior Director of the firm and Mr. Luis Urdaneta is listed as Vice President Director. Mrs. Maria Castellon stated that she is employed by Alcora Corp. and has been the president of B&R Products Inc. for the last 5 months. As explained by Mrs. Castellon, Mr. Rayner Urdaneta is the CEO and owner of Alcora Corp. and B&R Products Inc. while Mr. Luis Urdaneta is the vice president of Alcora Corp. The vice president of B&R Products Inc. is Mr. Warne Robert Millard III **(Exhibit #1)**.

The firm's office hours are Monday through Friday 8:00 AM - 6:00 PM. The firm also has two shifts for bulk (b) (4) and filling ((b) (4)). Mrs. Dillon stated that B&R Products Inc. has a total of (b) (4) full-time employees and (b) (4) part-time employees. The firm is an FDA establishment size (b) (4) based on gross annual sales figures according to information provided by Mrs. Castellon. The previous inspection was conducted on 08/16/2010 by the FDA with a classification of No Action Indicated (NAI). No objectionable conditions were noted during that inspection.

The firm does not have a history of adverse regulatory actions with the FDA, and the firm does not have a history of recalls with the FDA.

FMD-145 and post-inspectional correspondence should be addressed to:
Mrs. Maria Castellon
18721 SW 104th Ave.
Miami, FL 33157
Tel: 305-378-8528
Email: mcastellon@brpro.com

INTERSTATE (I.S.) COMMERCE

Mr. Ross stated that (b) (4) of incoming products originate from outside of the state of Florida. Mr. Ross also stated that approximately (b) (4) of the products are shipped/exported outside the United States, mainly to Latin America. In the near future, the firm plans to export (b) (4) products to Europe. According to Mr. Ross, conversations regarding logistics and testing of the products under European law are already underway.

Mrs. Dillon informed me that all products (100%) are sold wholesale. The firm does not sell its products at retail.

Mr. Ross provided information about the firm's top three suppliers outside of Florida, USA:

- (b) (4) (supplier of Capixyl)
- (b) (4) (supplier of Procataline)
- (b) (4) (supplier of Cola Det EQ-19, Cola Det EQ-20)

The firm's top customer is (b) (4) , with approximately (b) (4) of the product manufactured by B&R Products Inc. distributed through (b) (4) .

A reconciliation exam of the Cola Det EQ-19 (CH000377) lot# 61661B18 was completed with no discrepancies found **(Exhibit #2)**. The Cola Det EQ-19 lot# 61661B18 was received on 02/27/2018. The following interstate documentation was obtained: Bill of lading #(b) (4) dated 02/22/2018 from (b) (4) . located at (b) (4) documenting the shipment of Coladet EQ-19/Tote 3098-T **(Exhibit #3, Page 1)**. The following supporting documents were also collected for the Cola Det EQ-19 (CH000377) lot# 61661B18:

- Packing slip from (b) (4) . documenting (b) (4) totes of 2,250 lbs of Cola Det EQ-19 **(Exhibit #3, Page 2)**.
- Certificate of Analysis for Cola Det EQ-19 Lot# 61661B18 dated o2/23/2018. **(Exhibit #3, Page 4)**.

According to Mrs. Dillon, the firm promotes its products on the firm's website (http://www.brpro.com/) and social media. The firm owns (b) (4) for delivery purposes from the manufacturing building to the warehouse building located at 10200 SW 186th St. Cutler Bay, FL 33157. The firm does not add any labeling/promotional material to (b) (4) products because all finished products are transferred to (b) (4) . shares a space in the warehouse building of B&R Products Inc. Once the products are transferred to (b) (4) employees open the cases and create kits with different products. (b) (4) employees add labeling and promotional materials to these kits. During the

inspection, Mr. Carmelo Prieto asked a (b) (4) . employee for brochures and once Mr. Prieto had them, he provided to us **(Exhibit #4, #5 and #6)**.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

B&R Products Inc. has a variety of hair care products including shampoos, conditioners, hair creams, and styling aids for children and adults. The products are available in different sizes and packaging. The firm is a private label manufacturer; it does not have its own brand. Mrs. Dillon provided a product list that the firm manufactures for (b) (4) . **(Exhibit #7)**. These products are all subject to regulation under the Food, Drug & Cosmetic Act. Mrs. Dillon also provided a list of the top 5 (b) (4) shampoos and conditioners for 2017 and 2018 **(Exhibit #8)**.

The firm considers (b) (4) products as solely cosmetics and not over the counter drugs. (b) (4) performed clinical treatment studies (published in their website) and reported that (b) (4) ingredient users experienced benefits including a significant hair growth with an average increase in hair count **(Exhibit #39)**.

Labeling

(b) (4) . sent the containers with the imprint label, the induction safety seal, and the cap for their products to B&R Products Inc. warehouse. The firm does not add any brochures to (b) (4) products as this is done by (b) (4) The firm has no labeling agreement or statutory guaranty.

During this inspection, I collected labeling of the following containers:

- (b) (4) Renew Shampoo 8.0oz **(Exhibit #9, Pages 1-5)**
- Reshape Root Lifter 4.5oz **(Exhibit #9, Pages 6-10)**
- Rejuvabeads by (b) (4) 2.4oz **(Exhibit #9, Pages 11-14)**

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Maria Castellon, president – Mrs. Castellon is the firm's most responsible person as stated by her and her employees. She is employed by Alcora Corp. (parent company) and for the last 5 months, she has been the president of B&R Products Inc. Mrs. Castellon oversees all the operations of the firm. I observed her delegating and giving instructions to the firm's employees, including Mrs. Dillon to sign Form FDA 484, because as per the firm's legal department, she was not allowed to sign any FDA documentation. She provided administrative information during the inspection including the firm's gross annual sales. Mrs. Castellon was present at the firm during the inspection but did not accompany us. Mrs. Castellon is in the firm on a daily basis and was present at the closeout meeting. Mrs. Castellon reports to Mr. Rayner Urdaneta, CEO of the firm and the parent company.

Mrs. Joanne Dillon, director of QA/QC – Mrs. Dillon has been in the cosmetic industry for the last 25 years.

She has been with the firm and in her current position for approximately 2 years. Mrs. Dillon holds a bachelor degree (BS) in Animal Science with a minor in Chemistry. Also, she completed GMP training, ISO9000 training, and she is a certified auditor. She oversees the entire QC and QA department that is responsible for releasing raw, in-process and finished product batch releases, reviewing lab tests, retains, major customer complaints, and employees training. Mrs. Dillon maintained all the records associated with tests, complaints, and training. Mrs. Dillon accompanied us during the inspection and answered most of the questions and provided most of the documents requested. Mrs. Dillon reports to Mrs. Castellon and was present during the close out meeting.

Mr. Jamie Ross, senior vice president – Mr. Ross is in charge of technical services and manufacturing/research and development (R&D) at the firm. He has been working for the firm in the same position for the last 12 years. Mr. Ross is the firm's product formulator and has created the firm's formulas for the past 11 years. Mr. Ross is responsible for (b) (4) formulas and is knowledgeable about raw material and their properties. He answered all the questions regarding raw material, formulas, and changes to the formulas. Mr. Ross gives instructions on how to correct a problem when QC reports that the product is out of specification. He is one of the members of (b) (4) Scientific Advisory Board and leads a team of (b) (4) scientists. Mr. Ross reports to Mrs. Castellon and was present during the close out meeting.

(b) (6) **, regulatory affairs specialist** – (b) (6) has worked for B&R Products since October 2017 and is the lab contact person for the safety tests performed on ingredients/products. When (b) (6) receives a customer complaint, the information is transferred to (b) (6) who is responsible for making customer phone calls to gather all the relevant facts and information. She also fills out the corresponding form for each complaint **(Exhibit #33)**. (b) (6) reports to Mrs. Ross.

(b) (6) **, document control** – (b) (6) has been working with the firm for the last 3.5 years. (b) (6) is in charge of the retention and retrieval of R&D documents. She provided documentation to Mr. Goran Periz as per Mr. Ross. (b) (6) reports to Mr. Ross.

Carmelo Prieto, warehouse manager – Mr. Prieto has been working with the firm in the same position for the last two years. He is responsible for the shipping and receiving of products, and answered questions regarding these areas. He accompanied us during the warehouse walkthrough. Mr. Prieto reports to Mr. Gene Henning, Executive VP.

FIRM'S TRAINING PROGRAM

Employees receive new-hire and refresher training in Good Manufacturing Practices (GMPs), safety and Occupational Safety and Health Administration (OSHA) regulations. GMP training is given annually to all

employees. Mrs. Dillon gives the training in English and (b) (6) (QC Technician) gives it in Spanish. Training is classroom based with a power point presentation that lasts approximately one hour. Training is given to 15 to 20 employees at the same time.

Training related to the cleaning and sanitizing of equipment is provided to the employees that perform these duties by Mrs. Dillon only in English as the employees assigned to these duties are English speakers. The training is given in the manufacturing area with discussions and demonstrations.

A Review of training records showed that October 2017 was the last Cleaning and Sanitizing training given to employees by Mrs. Dillon. During September 2017 Mrs. Dillon and (b) (6) gave training related to GMP and Good Documentation Practices (GDPs).

MANUFACTURING/DESIGN OPERATIONS

The firm operates in three different buildings. The warehouse building has approximately (b) (4) and during this inspection, it was shared with (b) (4) . The manufacturing building has approximately (b) (4) . The firm does not have copies of a facility diagram for the manufacturing building however, the firm provided the original construction floor plans for pictures purposes **(Exhibit #37 Photo 29)**. A facility diagram from FDA inspection done on 08/23/2010 was also added **(Exhibit #10)**. The third building is the employees' breakroom, maintenance, retains and offices with an approximately (b) (4) . All buildings are within walking distance (0.6 miles or less). Mrs. Castellon stated that B&R Products Inc. tenant of the facilities that they use however, she couldn't specify the leasing company or to which corporation the buildings belongs.

(b) (4) for Men Shampoo + Conditioner Lot #18J0308038 was observed during the course of this inspection. The following flow chart relates to the production of this product:

(b) (4)

(b) (4)

Warehouse Receiving:

The warehouse is located at 10200 SW 186th St. Miami, FL 33157. Receiving/shipping personnel are responsible for inspecting all incoming raw materials and logging information into the firm's database. The firm verifies the condition of the boxes and that the products received were the ones ordered. Mrs. Dillon stated that the firm just started (two weeks ago) to perform pH and viscosity testing when the raw material is received. Records of these tests were not reviewed during this inspection. The firm does not sample and test raw materials for conformance with specifications to ensure the absence of filth, microorganisms, and or other adulterants prior to processing or usage. The firm's electronic system assigns the location where the incoming material will be stored. Raw materials are stored in closed containers and off the floor. Raw materials are maintained in containers that are labeled with identity, lot number, and control status (release or quarantine). The firm does not keep an assigned area for materials that fail to meet acceptance specifications (quarantine or rejected) however, are labeled with a color code label that identifies the purposes of it. A green sticker means "release", yellow sticker means "quarantine" and red sticker means "rejected". The color code is not always followed because during the inspection a white "release" label was found applied to a drum of Pomegranate Sage Fragrance Lot# (b) (4) Also, a yellow "release" label was applied to a bucket of Dermol 99 Lot# (b) (4) . The firm could not provide an explanation for these situations. The firm keeps the invoice and certificate of analysis in their facilities as hard copies. Bills of lading are mainly kept by the supplier but provided to the firm upon their request. Mrs. Dillon stated that the firm has raw material specification in place.

Transporting:

Based on demand, an order is placed and raw materials are delivered in the firm's truck from the receiving/shipping warehouse to the manufacturing building. Materials received should have a green sticker applied to it that means the raw material is released and able to be used. The release sticker is applied at the warehouse but does not necessary means that the raw material was tested.

Staging:

Employees weigh the raw material needed for the formulation using a floor scale that is calibrated (b) (4)

Pallets of the raw material needed for a formulation are prepared by the employees. During this inspection, I observed a pallet marked as incomplete because a raw material was missing in order to complete the materials needed for the formulation. I noticed (b) (4) drums of Pureact WS Concentrate on the pallet. One of the drums had the original green sticker applied at the receiving in the firm's warehouse with a weight of 500lbs. The other drum had a white sticker applied to it at the staging process. This drum was labeled as a total weight of (b) (4) . The batch record showed that the total amount of Pureact WS Concentrate needed for the formulation of (b) (4) Renew Shampoo Lot# (b) (4) was (b) (4) I asked Mrs. Dillon why the pallet has more Pureact WS Concentrate than needed (b) (4)). Mrs. Dillon called the manufacturing manager and she explained that the (b) (4)

. On 03/14/2018 and as per our request, the drum labeled as Pureact WS Concentrate Lot# (b) (4) and labeled as (b) (4) was weighed again by the employees. The employees informed us that the drum itself has a weight of (b) (4) . Pureact WS Concentrate was weighed (b) (4) as it is usually done by the employees. The weight shown on the floor scale was (b) (4). The employees also mentioned that even when the accurate weight of Pureact WS Concentrate is (b) (4) Weighing and measuring of raw materials are checked by the employee that performed this duty and signed with the employees' initials.

The firm provided their SOP 3.3 Weighing Procedure **(Exhibit #11),** but information is missing as well as signatures for elaborated, revised, approved and date entries. As per this SOP, a plastic bag or an appropriate sized drum, jar or cup should be (b) (4) . This was not observed during our request to re-weigh the Pureact WS Concentrate to compare it with the weight recorded on the label stick for the drum. I observed employees automatically (b) (4) (drum weight) from the weight shown on the scale. This practice was also explained to me by the employees. Also, the SOP stated, (b) (4) This SOP is missing information needed by the employees regarding what information should be recorded. The relevance of information missing in this SOP is important because we observed Pureact WS Concentrate with an inaccurate weight recorded in the drum (b) (4)). On 03/14/2018 Mrs. Dillon stated that the firm has an updated version of this SOP, however a copy was not provided during this inspection.

Compounding:

(b) (4) . The compounding process was not observed during this inspection. The firm provided a copy of their SOP 3.5 Batching Process **(Exhibit #12)**. (b) (4) . Prepared pallets with the raw materials needed are

brought to the reactors area to be mixed and blended. The addition of raw materials is done in the same order that is written in the batch ticket. The reactors have the ability to heat or cool the in-process product depending on the formulation. The firm does not re-use the raw material drums. A third-party contractor takes them for recycling purposes. Reactors are identified with their contents including product name, formula, lot number and quantity. The blending of a product could take between (b) (4) if QC releases it, based on the fact that the product meets the specifications given by Research and Development. Viscosity and pH are tested while the product is (b) (4) If pH or viscosity is out of specifications, the product will remain in the (b) (4) until R&D issues instructions on how to adjust the product to specifications. According to Mrs. Dillon, 25% of the time, the products need adjustments in order to meet the specifications. Out of (b) (4) batch records reviewed during this inspection, all associated with customer complaints, 6 of them where adjusted mainly due to low viscosity issues (b) (4) higher viscosity (b) (4) and higher pH ((b) (4) When the in-process product is within specifications, QC releases it and it is pumped from (b) (4) .

The firm (b) (4) . Also, the firm does not have dedicated hoses for pumping product from the (b) (4) . Dedicating hoses for specific purposes was discussed with the firm at the close out meeting. We observed that the firm does not label hoses that are cleaned and sanitized, contrary to what is established in their SOP 4.3.1. **(Exhibit #13)**. We observed cleaned and sanitized hoses without protective caps in both ends to prevent contamination (Observation 1-3). Also, we observed a hose used to drain a reactor with an end inserted into the waste drainage system of the firm. Since the firm shares equipment and does not identify cleaned and sanitize hoses, proper measures need to be taken to prevent contamination resulting from the equipment. I also observed reactor (b) (4) with the lid open while processing product (Observation 1-1).

(b) (4) **Liner:**

The in-process product leaves the reactor via a hose connected to a pump to an (b) (4) liner. The (b) (4) liner system operates with (b) (4) . The system is a (b) (4)

QC verifies that all liquid drawn from the liners belongs to the same lot number. Also, QC takes a sample for visual inspection (absence of foreign material inside, color and texture). (b) (4)

Filling line:

Once the product is drawn from the (b) (4)

(b) (4)
(b) (4) with the induction seal and the cap. Labeling information is pre-printed on the bottle. The lot number is manually added to the filling machine by an employee, and later automatically embedded on the bottle by ink jetprinter. Bottles are (b) (4) by the machine. QC will pull out finished products at the (b) (4) of the production for finished product tests and retains. Every (b) (4) , employees take (b) (4) samples for weight checks. Bottles with finished products are (b) (4) deposited in boxes by the employees. (b) (4) for Men Shampoo + Conditioner Lot #18J0308038 was packed in cardboard boxes, 36 units of 8 oz. per case and labeled as such.

On 03/12/2018 during the production of (b) (4) Black Shampoo + Conditioner Lot#18J030839, I observed cloth adhesive tape on the hopper discharge piece. This piece comes in direct contact with the product bottles during filling. The employee indicated that due to a leak in this area, the cloth adhesive tape was added to resolve an issue, while an "O" ring was changed. Mrs. Dillon instructed staff to change the ring and to discontinue/prevent the use of cloth tape on the equipment.

Filling lines are cleaned and sanitized before filling starts and between production runs. On 03/19/2018 we observed empty containers of (b) (4) Rejuvabeads (b) (4) that were not returned to storage and were left unattended and uncovered in filling line (b) (4) (Observation 1-5).

The firm keep (b) (4) finished products from each lot for retains purposes. The retains are kept for (b) (4) ears.

Shipping:

Cases of (b) (4) products are stacked in pallets and sent back to the firm's warehouse where they are transferred from B&R Products Inc. to (b) (4) . employees will prepare kits with different products along with promotional material. (b) (4) . is responsible for further shipping to their customers.

Cleaning and Sanitation Procedures:

The firm has an SOP for Cleaning and Sanitization Manufacturing Equipment **(Exhibit #13)** as well as Work Instruction for Manufacturing Tanks/Holding Tanks/Totes Cleaning and Sanitization **(Exhibit #14)**. During the inspection, I observed residues of products in the upper part of reactor (b) (4) and in the lid (Observation 1-2). As per log book, cleaning was performed on the equipment on 03/08/2018 and a re-cleaning performed on 03/12/2018 before this inspection. Reactor (b) (4) was ready to process a new batch of Volume Revive Shampoo Lot# (b) (4) . Mrs. Dillon pointed out the old residues in the reactor to an employee and instructed him to re-clean it again. Reactor (b) (4) was cleaned again using a textile cloth and (b) (4) (cleaner agent). Reactors are cleaned and sanitized (b) (4) but if the reactor is not in use for (b) (4) , a re-sanitation will be done. The re-cleaning that I observed on 03/12/2018 was not logged in the

B&R Manufacturing Tank Cleaning record **(Exhibit #15),** contrary to what is stated on item #14 of the Work Instruction for Manufacturing Tanks/Holding Tanks/Totes Cleaning and Sanitization **(Exhibit #14)**.

During this inspection, I also observed the cleaning and sanitation of filling line (b) (4). Hoses are cleaned with (b) (4) .(b) (4) (quaternary disinfectant) previously prepared by QC are poured through the hose. The hose is connected to a pump that will circulate the sanitizer solution for (b) (4) . After (b) (4) , the solution is flushed from the hose and discarded in the ware washing sink. New(b) (4) . I observed that the firm does not label hoses that are cleaned and sanitized contrary to what it is established in their SOP 4.3.1 **(Exhibit #13)**.

Pieces and equipment of the filling line are dissembled and transported via a rolling cart to the designated cleaning area. Dissembled parts are washed with hot water until residues are washed out. (b) (4) is sprayed on the parts and the transporting cart. Parts were assembled again in the filling line. Products that spill on the floor or in the transporting cart are wiped out with a paper towel and then (b) (4) is poured into it and wiped again.

Pest Control:

During this inspection pest activity was not observed. The service is given in a (b) (4) basis by (b) (4) (Manufacturing building) and by (b) (4) (warehouse building). The firm has a Pest Control Program SOP **(Exhibit #17)**.

(b) (4) **Water System:**

The firm's (b) (4) water is built by (b) (4) and the maintenance is given by (b) (4) (b) (4) . The (b) (4) water system is used to(b) (4) water, a major component in manufacturing (b) (4) products. The system consists of a water softener, UV lights, reverse osmosis, and continuous (b) (4) unit. Records from 2017 provided by the firm show that micro tests performed to the (b) (4) water were done at least (b) (4) ; however micro tests were only performed during the months of November and December **(Exhibit #16)**. The system was cleaned and sanitized by (b) (4) on 10/31/2017 and filter maintenance was done in February 2018. According to Mrs. Dillon, the firm flushes water system lines with (b) (4) rinses with water, and checks the removal of (b) (4) with test strips.

The firm has (b) (4) water drops located in the manufacturing area. The firm identifies and has monitoring data on (b) (4) of the drops that is in use. (b) (4) apparently unused drops are not monitored and are wrapped with plastic covering. The unused water drops are L-shaped, located below the main (b) (4) water line, and apparently contain stagnant water. Mr. Periz pointed this situation to Mrs. Dillon.

(b) (4) water is transferred from a (b) (4) . We observed water holding tank without a lid or cover on approximately 1 ft. diameter opening on the top of the tank. We pointed this situation to Mrs. Dillon.

Raw Material:

Mrs. Dillon stated that the formulation of (b) (4) products was changed. Cola Det EQ-19 **(Exhibit #18)** was the surfactant used by the firm for (b) (4) products until October-November 2017. (b) (4) (Cola Det EQ-19 supplier) was affected by hurricane Harvey and could not supply EQ-19 anymore, however the supplier offered Cola Det EQ-20 (another surfactant) that was available at another facility **(Exhibit #19)**. Mrs. Ross informed that raw material tests for EQ-20 were not performed but finished product tests were done to products with EQ-20. Also, Mr. Ross informed that an antimicrobial challenge test for EQ-20 was in process. Cola Det EQ-19 and ColaDet EQ-20 exhibit similar characteristics and the major difference according to Mrs. Ross was the change of one of the ingredients, from (b) (4) . Mr. Ross explained that based on the raw material firm ((b) (4) research, the firm agreed to the change believing it was a safer choice.

In January 2018 the firm switched back to Cola Det EQ-19 due to the number of customer complaints that the firm started to receive for that date. Review of firm's batch records revealed that products that do not contain Cola Det EQ-19 or Cola Det EQ-20 as part of their formulation, are also associated with customer complaints.

The firm provided information for the following raw materials **(Exhibit #20 Pages 1 to 6)**:

- Crodasorb UV-283 (anti-static and hair conditioning agent; light stabilizer)
- SugaQuat (surfactant, skin conditioning agent)
- ColaTeric LMB (surfactant, anti-static, hair and skin conditioning agent)

The firm also provided the specifications data sheet for Procataline and Capixyl **(Exhibit #20 Pages 7 and 8)**.

Batch records:

It is the firm's practice to add the labels ((b) (4)) of all raw materials compounded in a batch to the batch records as proof that the raw material was added. As mentioned before, these labels do not reflect the accurate weight of the raw material. Accurate weight for raw material also is not recorded in the batch record. The batch records already have the measured weight prefill. Employees only add their initials and lot # of the raw material in the batch record.

Also, Mrs. Dillon explained that the specifications for 8.0oz bottles were changed due to aesthetic issues.

(b) (4) . marketing department decided to move to a (b) (4) bottle even when the actual weight declared in the bottle is 8.0z. The batch records do not provide instructions, explanations or justifications to overfill the bottles. Mrs. Dillon added that the notification from (b) (4) was sent via email.

A total of (b) (4) batch records associated with adverse event reports filed with the FDA were reviewed during the inspection. The following discrepancies were noticed in 10 of them:

- Batch record (b) (4) (b) (4) Renew Balance Shampoo (8.0 fl.oz)
  - Finished product ideal weight is between (b) (4) but samples taken every (b) (4) show an average of (b) (4). Out of (b) (4) samples taken for weighing, only (b) (4) of them were in the range established by the firm. The batch was released.
  - Product manufactured with Cola Det EQ-19.
- Batch record #17J1016170 (b) (4) Renew Balance Shampoo (8.0 fl.oz)
  - Manufactured under formula (b) (4) which is the same formula used for Batch record (b) (4) however; a change of ingredient was done. Batch record (b) (4) has (b) (4) of Rejuvenique Hair Oil blend while Batch record (b) (4) treatment oil.
  - Finished product ideal weight is between (b) (4) . This range varies from the weight specifications for the same product manufactured a week before (Batch record (b) (4)). As per Mrs. Dillon, since the volume can't be measured at the firm, they use specific (b) (4) to make sure that the weight listed in the container is the right one. The ideal weight is calculated by the (b) (4) . Mrs. Dillon stated that when the (b) (4) . The batch was released.
  - Product manufactured with Cola Det EQ-19.
- Batch record #18J0103004 (b) (4) Renew Balance Shampoo (8.0 fl.oz)
  - This batch was adjusted because it was out of specification due to higher viscosity ((b) (4) maximum allowed) but there is no evidence that raw material was added to adjust the viscosity (label of the raw material added is missing in the batch record and also the raw material is recorded as N/A in the material added section). A handwritten note stated that the raw material was added to bring the product back into specification.
  - A raw material used to adjust pH was recorded as N/A in the batch record but a label of the raw material with lot # and weight is attached to the batch record as if the material was added.
  - The ideal weight for this product has a range of (b) (4) . The average weights for the product according to the batch records were (b) (4) . Both weights have the signature and date of the employee that weighs them and recorded them, but the review and approval signatures are missing. The batch was released.
  - Product manufactured with Cola Det EQ-20.
- Batch # 17J1120274 (b) (4) Renew Balance Shampoo (8.0 fl.oz)
  - Finished product ideal weight is between (b) (4) but samples taken every (b) (4) show averages of (b) (4) . All averages were signed by the employee who took the sample and recorded the information. Also, the approval signature is in the batch

record. The batch was released.

- Product manufactured with Cola Det EQ-20.

- Batch #17J0720180 (b) (4) Renew Shampoo (8.0 fl.oz)
  - Finished product ideal weight is between (b) (4) but samples taken every (b) (4) shows averages of (b) (4) . There is a note in the batch record that specific gravity changed and the weights were recalculated on 08/02/2017 during the morning. The new range was between (b) (4) with a calculated average of (b) (4). The batch was released.
  - Product manufactured with Cola Det EQ-19.
- Batch #17J1012134 (b) (4) Intense Repair Treatment Shampoo (8.0 fl.oz)
  - Batch was adjusted because the minimum viscosity specification is (b) (4) and the product had (b) (4) .
  - Finished product ideal weight is between (b) (4) but samples taken every (b) (4) show averages of (b) (4) . These averages were signed by the employee who took it and recorded the data. The batch record also has the approving signature. The batch was released.
- Batch #17J0705035 (b) (4) Intense Repair Treatment Conditioner (6.0 fl. oz.)
  - Batch was adjusted because the pH was out of specification ((b) (4) vs a maximum specification of (b) (4)).
  - This batch was adjusted because it was out of specification, but there is no evidence that a raw material was added to adjust the pH (label of the raw material added is missing in the batch record) and also the raw material is recorded as N/A in the material added section. The batch was released.
- Batch #17J0830327 (b) (4) Rejuvabeads Split End Mender (2.4 fl. oz.)
  - Batch was adjusted because the pH was out of specification (b) (4) vs a maximum specification of (b) (4)).
  - Label for the raw material used to adjust the pH is not in the batch record. Batch record section of added raw material is missing the lot number of the raw material used to bring back the product to specifications.
  - Finished product ideal weight is between (b) (4) but samples taken every (b) (4) shows an average of (b) (4) . The batch record has the signatures of the employee(s) who recorded it and approved it. The batch was released.
- Batch #17J1113202 (b) (4) Smoothing Deep Conditioner (6.0 fl. oz.)
  - One raw material is missing the weight on the label that the firm adds to the batch record as a proof that the material was compounded. Batch record weight section is already pre-printed and pre-filled; employees only add the lot # and their initials (not the accurate weight). The batch was released.
- Batch #17J0921100 (b) (4) Intense Repair Treatment Shampoo (8.0fl. oz.)
  - Batch was adjusted because of low viscosity (b) (4) vs a minimum specification of (b) (4)).
  - Instructions to bring back the product into specification were to (b) (4) of a specific raw

material. The label of the raw material shows a weight of (b) (4) while in the added raw material section for compounding (b) (4) in it. The batch was released.

Mrs. Dillon stated that the firm goes over or under based on Maximum Allowable Variation (MAV). According to the National Institute of Standards and Technology (U.S Department of Commerce), maximum allowable variations for packages labeled by liquid and dry volume (if the labeled quantity is more than 7.50 fl oz. to 11.75fl oz.) is 0.38fl oz. Using this database (b) (4) bottles are labeled 8.0 fl oz. (226.796g) and could not have more than 8.38 fl oz. (237.5688g). Batch records previously explained exceed the establish MAV.

Laboratory Tests

The firm uses (b) (4) . to perform microbiological challenge tests for new formulas. The firm provided the report for (b) (4) Renew Balance Shampoo with formula (b) (4) and Lot (b) (4) . This formulation was used to manufacture (b) (4) Renew Balance Shampoo Lot# 18J0103004 associated with a customer complaint. The firm did not provide the identity, strength, stability, solubility, purity and chemical composition to the lab. The lab reported that based on the Antimicrobial Effectiveness Test results, the product would meet the requirements for a Category I Preservative System. Based on the Cosmetics, Toiletry, and Fragrance Association Microbiology Guidelines (CFTA) the product is considered well preserved **(Exhibit #21)**.

Microbiological challenge test performed to (b) (4) Black Shampoo + Conditioner formula with formula (b) (4) and Lot (b) (4) . This formulation was used to manufacture (b) (4) Black Shampoo + Conditioner Lot #17J1102035 and 17J1129326 both associated with customer complaints. The firm also did not provide the identity, strength, stability, solubility, purity and chemical composition to the lab. The lab reported that based on the Antimicrobial Effectiveness Test results, the product would meet the requirements for a Category I Preservative System. Based on the CFTA the product is considered well preserved **(Exhibit #22)**.

The firm also provided the report for the challenge test performed to (b) (4) Revive Shampoo with formula (b) (4) and Lot (b) (4) . This formulation was used to manufacture (b) (4) Revive Shampoo Lot# (b) (4) that was in process on filling line (b) (4) during this inspection. The firm did not provide the identity, strength, stability, solubility, purity and chemical composition to the lab. The lab reported that based on the Antimicrobial Effectiveness Test results, the product would meet the requirements for a Category I Preservative System. Based on the CFTA the product is considered well preserved **(Exhibit #23)**.

(b) (4) . also performed the microbiology tests for finished products. The firm keeps a log book for the pH and micro results of finished products **(Exhibit #24)**.

(b) (4) is an independent, non-profit, scientific research and education organization that performed hair damage testing for (b) (4) The products used in the study were (b) (4) Intense Repair

Shampoo and (b) (4) Intense Repair Treatment Conditioner. The tests were done using a traditional dosage ((b) (4)) and a double dosage ((b) (4)) based on the product instructions "massage a generous amount on wet hair". The products were applied alone and in combination with virgin hair and to bleach/colored hair with and without heat treatments (blow-dry/flat iron for(b) (4)). Based on the results, (b) (4) reported that there are no indications that the application of the two (b) (4) products led to reduced tensile strength, manageability issues or compromised surface (cuticle) structure **(Exhibit #25)**.

Damage Reduction test was also performed by (b) (4)) using similar techniques and amounts to the one used by (b) (4) . The tests were performed for (b) (4) Renew Shampoo, (b) (4) Restore Leave-in Conditioner, (b) (4) Volume Revive Shampoo, (b) (4) Volume Revitalize Conditioner and (b) (4) Black Shampoo + Conditioner. According to the results, the products showed no effect on the surface of virgin hair and on bleached dyed hair. (b) (4) also reported that the products slightly contribute to improve the smoothing of the cuticle when compare to the bleached and dyed hair **(Exhibit #26)**. Hair combability measurements tests (softness of the hair fiber surface, reduction of wrinkles and closing of the outer cuticular layer of the fiber) were also performed with these same (b) (4) productsapplied to virgin hair, as well as, bleached/dyed hair. According to the results obtained, both types of the hair were easier to comb when pre-treated with above listed products, presumably by reducing the wrinkles and closing the outer cuticles of the hair fibers in treated samples **(Exhibit #27)**.

The last test performed by (b) (4) to the products mentioned above was the evaluation of the tensile properties of hair fibers. Tests were performed on (b) (4) product-treated or non-treated virgin and bleached/dyed hair, with or without heat treatment (flat iron). (b) (4) reported that the application of (b) (4) products did not have negative effect on mechanical properties of heat-treated, or untreated, virgin or bleached/dyed hair, compared with the hair subjected to the same conditions but that was not pre-treated with (b) (4) products. **(Exhibit #28)**.

The firm also provided Product Information Files (PIFs) for (b) (4) products prepared by (b) (4) The PIFs include description of the products, cosmetic product safety reports, finished product safety data sheets, method of manufacture, GMP Certificate, and animal testing statements. The PIFs include safety summaries for each ingredient, and state that all of the ingredients in a (b) (4) product have a history of use in cosmetic and toiletry products however, ingredients that are prohibited under EU Cosmetics Regulations, restricted when used beyond the allowed authorized conditions, with toxicological data incompatible with the intended concentration, with insufficient toxicological data and/or that are not properly characterized with regard to purity and analytical composition were excluded. The PIFs stated that the products are considered to be protected from microbial growth, and the product formulations are based on known ingredients with history of safe use in cosmetic products. According to the (b) (4) (the safety assessor of(b) (4) products), the concentrations of ingredients appear to be within recommended limits. The (b) (4) based their conclusions on several criteria including ingredient concentrations, reviews of literature, anonymous toxicological ingredient information supplied by manufacturers, assessor's data on file, manufacturer-contracted safety studies, and (b) (4) calculations of margins of

safety.. According to this report, some (b) (4) (b) (4) products were tested for irritation/sensitization potential using human dermal patch test and were rated as *Not Irritant* **(Exhibit #29)**.

The firm provided via email the following (b) (4) products safety assessments to Mr. Goran Periz as per his request **(Exhibit #30)**:

1. Black for Men 2-in-1
2. Intense Repair Conditioner
3. Intense Repair Treatment
4. Intense Repair Treatment Shampoo
5. Only For You Blow-Out Cream
6. Only For You Clarifying Shampoo
7. Only For You Curl Cream
8. Only For You Eye Wonder Eyelash & Brow Enhancer
9. Only For You Thickening Spray
10. Refinish Control Hairspray
11. Rejuvabeads Split-End Mender
12. Rejuveniqe Oil Intensive
13. Renew Balance Shampoo
14. Replenish Balance Masque
15. Reshape Root Lifter
16. Restore Leave-in Conditioner
17. Revitalize Volume Conditioner
18. Revive Volume Shampoo
19. The Champ Dry Shampoo

Color Additives

As per Mr. Ross Ext. D&C Violet No. 2 and D&C Red No.33 are used for the Platinum Conditioner **(Exhibit #32)**. Mr. Ross added that Caramel color is also used in some products, however this color additive is exempt from batch certification. Mrs. Dillon added that two weeks before this inspection, the firm started using "natural" colors for their products. However, any coloring added to the product for purpose of changing or adding the color of the product is artificial coloring.

MANUFACTURING CODES

The firm uses an (b) (4) code on all finished products to identify each batch/lot number. For example, on 03/14/2018, I observed the following manufacturing lot code embossed (via machine) onto the top back part of the (b) (4) for Men Shampoo + Conditioner being filled in line(b) (4)

(b) (4)

(b) (4) digits of the current year

(b) (4)

(b) (4) that the batch was created

(b) (4) that the batch was created

(b) (4) that represent the sequential number of the month

In the past, the letter was a representation of the month but the firm changed to (b) (4) system and this new system does not change the letter. The firm decided to leave it as (b) (4) in all the products.

COMPLAINTS

(b) (4) Standard Operation Procedure for Product Complaints **(Exhibit #32)** established that their customer service department will receive and handle initial customer contact, obtaining the initial information from the customer and responding to the customer. The information will be transferred to (b) (6) (regulatory affairs specialist of B&R Products Inc.), to develop a complaint intake form that will be given to B&R Products Inc. QA/QC Department. Mrs. Dillon does the investigation **(Exhibit #33, Page 1)**. If the complaint is related to (but not limited) an allergic reaction that can affect the skin, eyes, or mouth an Adverse Event/Undesirable Effect Form (**Exhibit #33, Page 2)** will be filled out. (b) (6) has a background in pharmacy and is the assigned person to make the phone call (once the information is received from (b) (4) to follow up with the Adverse Event Report. (b) (6) informed me that (b) (4) is outsourcing the handling of complaints to a third party company with health professionals.

According to B&R Products, Inc. Standard Operation Procedures for Customer Complaints **(Exhibit #34),** a log of the complaints will be created and where sufficient samples are provided by the customer, product testing will be done. Mrs. Dillon explained that if the customer provided the lot number, she verifies if the retains are present and enough product is available because sometimes a lot number was already tested for a previous complaint. If deemed necessary, the retains are tested for compliance with the specification (pH, viscosity, and microbiology). She also reviews batch records to see if there was any deviation.

A review of the firm's customer complaints log book shows a total of 29 records for the first two months of 2018 **(Exhibit #35)**. Customer complaints include: hair loss, rash (head, neck, and ears), falling of hair, hives

on face, itching, hair loss, red scalp inflammation, headaches, bumps in the hairline, sores, tingling scalp, and burning sensation, among others. Firm's records show that even when customers provided the lot number of the product, not always was a re-test of the retain done as specified on B&R Products Inc. SOP Number 12.1 **(Exhibit #34)** "If samples are not provided by the customer, batch retains for the corresponding lot number(s) will be retested." (i.e, complaint #13034 for rash on head, neck, and ears but the investigation conducted by the firm was to review records for the micro tests done to the product). For the complaints that retains were tested, the firm found that the product met the specifications.

Complaint #13032 is about a different smell of the product and hair feeling dry. The firm's investigation was that the "formula was changed from (b) (4) This stopped the separation and changed the color to a more white appearance. Slight difference noted on old vs new formula of more dryness."

Complaints #13053 and #13054 are related to hair loss breakage and broken hair respectively and the customer provided the product lot numbers. The firm records showed "retains to be tested" however; no tests were attached to these records.

Complaint #13042 was due to red scalp and inflammation with bumps after using the product for several weeks. Customer provided the product lot number but there are no records that an investigation was conducted.

The symptoms reported to the firm are similar to the ones reported by complainants to the FDA including: sores on the scalp, hair breakage, itching, blisters, sores, peeling of the scalp, burning sensation, and hives among others (i.e., complaints ID 152569, 152570, and 152577).

Hair loss has been reported on 7 different occasions to the firm however; details regarding any permanent hair loss are not recorded in the firm's complaint files. The most common advice given to customers was to stop using the products immediately. One customer reported to be allergic to (b) (4) which is one the preservatives used in (b) (4) products.

According to the firm, the products with higher number of complaints are:

- (b) (4) Renew Shampoo – (b) (4) units sold from January 2017 to February 2018
- (b) (4) Restore Leave-in Conditioner – (b) (4) units sold from January 2017 to February 2018
- (b) (4) Volume Revive Shampoo – (b) (4) units sold from January 2017 to February 2018
- (b) (4) Revitalize Conditioner – (b) (4) units sold from January 2017 to February 2018
- (b) (4) Black Shampoo + Conditioner – (b) (4) units sold from January 2017 to February 2018

Leave-in products do not potentiate more adverse event reports that washed out products.

RECALL PROCEDURES

The firm has a written recall procedure and is capable of tracking products **(Exhibit #36)** that applies to all products manufactured and/or distributed by B&R Products Inc. According to the firm's SOP, the firm will order a recall after the Director of Quality (Mrs. Dillon), the Senior Vice-President of Technical Services (Mr. Ross), and the Senior Vice President of Strategic Planning (not listed in the firm's organizational chart) decide a recall strategy.

I asked Mrs. Dillon if a recall for (b) (4) products was ever considered by the firm and she said that the firm did not initiate a recall because their testing does not indicate that there is anything causing a problem to the products. She added that if the product was contaminated or a serious adverse event is filled, B&R Products, Inc. will initiate a product recall through (b) (4) As of 03/13/2018, the firm did not have any discussion regarding a potential recall due to the high number of customer complaints.

The firm does not perform mock recalls, however original lot numbers of raw material are added to the batch records. Finished product lot number is assigned by the (b) (4) system that allows the firm to trace back a product up to the supplier level including the date the material was received in the firm. The firm keeps documentation needed in order to trace back a product (invoices, packing slip, batch records) and the supplier lot number assigned to a raw material does not change.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483
OBSERVATION 1

Your cosmetic was prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.

Specifically,

1) On 03/12/2018 I observed reactor (b) (4) located in the manufacturing room with an open lid while (b) (4) for Men Shampoo + Conditioner Lot# (b) (4) was held inside as an in-process product.

2) On 03/12/2018 I observed residues of products in the upper part of reactor (b) (4) and in the lid after a cleaning was performed to it on 03/08/2018 and a re-cleaning performed on 03/12/2018. Reactor (b) (4) was ready to process a new batch of hair care product. The lid of reactor (b) (4) was open. Reactors (b) (4) and (b) (4) are located next to each other.

3) On 03/12/2018 I observed 3 white hoses used to pump product to the hopper of the filling lines resting on a table near filling line (b) (4) The hoses were already cleaned and sanitized and both ends were without the protective caps that serve as a method to prevent contamination, leaving the interior surfaces exposed to the environment.

4) On 03/12/2018 a personal item (employee jacket) was stored in close proximity to filling line (b) (4) while (b) (4) Black Shampoo + Conditioner Lot# (b) (4) was being processed in this line. The jacket was specifically located next to the air hose used by this filling line and a white hose used to fill the hopper with a product.

5) On 03/19/2018 I observed that empty containers of (b) (4) Rejuvabeads (2.4oz) Lot# 18J0305030 were left uncovered and exposed in filling line (b) (4) after the employees finished their working day. The containers have an open end where the product is filled in.

Reference: FDCA 601(c)

Supporting Evidence and Relevance:

1) **Exhibit #37, Photo 10** shows reactor (b) (4) with the lid open while (b) (4) for Men Shampoo + Conditioner Lot# 18J0308038 was processing inside it. Reactor (b) (4) was exposing the in-process product to the environment.

2) **Exhibit #37, Photo 21** shows residues of products in the upper part of reactor (b) (4). Also, the lid of this reactor was open exposing these particles to the environment. Reactor (b) (4) is located next to reactor (b) (4) that was also found processing product with the lid open. Employees were ineffectively cleaning the reactor.

3) **Exhibit #37, Photo 8** shows one of the previously cleaned and sanitized hoses without the protective caps leaving the interior surfaces exposed to the environment.

4) **Exhibit #37, Photo 28** show an employee jacket near filling line (b) (4) that was processing bottles of (b) (4) Black Shampoo + Conditioner Lot#18J0308039. The jacket was hanging next to an air hose and a white hose used by the filling line to process product.

5) **Exhibit #37, Photo 18** shows empty containers that were left in the filling line (b) (4) with an open end exposing the interior of the container to the environment.

Discussion with Management:

1) Mrs. Dillon stated that the employees working in this area (compounding and QC) will be re-trained to make sure the lids are closed all the time. Re-training will occur within 10 days.

2) Mrs. Dillon stated that maintenance employees will be re-trained again with an emphasis on the proper cleaning and sanitation procedures. Re-training will occur within 10 days.

3) Mrs. Dillon informed me that employees also will be re-trained as per SOP 4.3.1 Cleaning and Sanitization of Manufacturing Equipment. Re-training will occur within 10 days.

4) Mrs. Castellon affirmed that she already had a meeting with the employees regarding the practices of storing personal items. Mrs. Castellon committed that the firm will verify that employees have lockers available for them. A third party company will provide more lockers as needed. Also, Mrs. Dillon said that a re-training of GMP compliance will be given to the employees. Provision of lockers and training will be done within 30 days.

5) Mrs. Dillon stated that a re-training of firm's GMP including line clearance will be given to the employees. Also, she will verify that line clearance is included in the SOP and if not, it will be added. Mrs. Dillon estimates the fulfillment of these tasks within 30 days.

REFUSALS

On 03/14/2018 Mrs. Dillon informed us that as per the firm's legal department (Mr. Tom Hoolihan), she is not allowed to provide copies of the batch records requested, formulas and raw material specifications. Mr. Goran told to Mrs. Dillon that raw material specifications are not unique to the firm and are usually given by the supplier as part of the shipment. Mrs. Dillon told Mr. Goran that those were the instructions of the legal department. At that point, I informed Mrs. Dillon that we will stop and break for lunch in order to seek guidance from the agency upper management. As instructed, we returned to the firm and I asked Mrs. Dillon if there was any change from the previous instructions but she said that legal department hasn't changed their point of view. I read the back part of the Form FDA482 where it states: "Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records" . Mrs. Dillon left her office as she requested time to inform the attorneys about what was read and because Mr. Tom Hoolihan already contacted (b) (4) (an attorney located in (b) (4) for the firm (b) (4)). She returned a couple of minutes after to ask if the batch records requested are associated with Adverse Event Reports filled with the FDA. I replied to her "Yes". Mrs. Dillon returned to the office and said that in about (b) (4) the attorneys will have an answer. Later on, Mrs. Dillon informed us that Mr. Hoolihan would like to set up a meeting with Mr. Ellison to see what information can be provided to FDA investigators because their interpretation of the law is that records are required for medical devices. I pointed Mrs. Dillon to the FD&C Act Section 301(e) Prohibited Acts (refusals to provide copies of records). Mrs. Dillon took notes about the FD&C Act but stated that at this point she can't do anything as instructions were given verbally to her by Mr. Hoolihan. After conversations between

Mr. Ellison and HAFE4 upper management, I was instructed not to request copies of the batch records.

GENERAL DISCUSSION WITH MANAGEMENT

On 03/20/2018 during the close out meeting I discussed the following item with Mrs. Castellon, Mrs. Dillon, and Mr. Ross:

- A hose was connected to a pump and the other side was inside the firm's drain **(Exhibit #37 Photo 9)**. According to Mrs. Dillon, the hose was used to drain a reactor, however to avoid a backflow or environmental contamination that could harm the products the firm will change this practice and proposed to have dedicated hoses just to drain the reactors. One of the firm's proposals was to use shorter hoses for this purposes or color-code the hoses.

SAMPLES COLLECTED

The following products were collected as per OCAC during the inspection:

- Sample #1043901 - (b) (4) Renew Balance Shampoo 8.0oz Lot# 18J0223202. Sub samples #1043901 1a to 10a are the samples and #1043901 1b to 10b are the 702(b) portion.
- Sample #1045853 1a and 1b (4oz each one) of Cola Det EQ 19 (raw material) – Lot (b) (4)
- Sample #1045853 2a (8oz in total) of Renew Shampoo (finished product) – Lot# 18J0223202
- Sample #1045853 3a and 3b (4oz each one) of SugaQuat S-1210 (raw material) – Lot# (b) (4)
- Sample # 1045853 4a and 4b (4oz each one) Revive Shampoo (finished product) – Lot# 17J1220134
- Sample # 1045853 5a and 5b (4oz each one) Cola Det EQ20 (raw material) – Lot# (b) (4)
- Sub sample 1a (8oz) (b) (4) Renew Shampoo – Lot# 18J0223202
- Sub sample 2a (0.5oz) of (b) (4) Black Shampoo + Conditioner – Lot# 17J1127304
- Sub Sub sample 3a (0.5oz) of (b) (4) Renew Shampoo – Lot# 17J1120274
- Sub sample 4a (0.5oz) of (b) (4) Smoothing Deep Conditioner – Lot# 17J1113202
- Sub sample 5a (0.5oz) of (b) (4) Intense Repair Shampoo – Lot# 17J1012134
- Sub sample 6a (0.5oz) of (b) (4) Renew Shampoo – Lot# 17J1009100
- Sub sample 7a (0.5oz) of (b) (4) Intense Repair Shampoo – Lot# 17J0921100
- Sub sample 8a (0.5oz) of Rejuvabeads by (b) (4) – Lot# 17J0830327
- Sub sample 9a (0.5oz) of (b) (4) Renew Shampoo

- Sub sample 10a (0.5oz) of (b) (4) Intense Repair Treatment – Lot# 17J0705035
- Sub sample 11a (0.5oz) of (b) (4) Renew Shampoo – Lot# 17J0627158
- Sub sample 12a (0.5oz) of (b) (4) Renew Shampoo – Lot# 18J0103004

VOLUNTARY CORRECTIONS

On 03/12/2018 after I observed reactor (b) (4) with the lid open while (b) (4) for Men Shampoo + Conditioner (Lot# 18J0308038) was held inside as an in-process product, Mrs. Dillon immediately called and employee and requested to close the lid. Mrs. Dillon explained that it was open because QC was performing tests to the in-process product however, this was not observed.

On 03/12/2018 after I observed residues of products in the upper part of reactor (b) (4), Mrs. Dillon asked an employee to re-clean this-reactor. I observed the employee cleaning the reactor with a cloth and (b) (4) as the cleaner agent. This re-cleaning was not added to the B&R (b) (4) Manufacturing Tank Cleaning Log.

On 03/12/2018 I observed 3 cleaned and disinfected hoses without the protective caps. Mrs. Dillon asked an employee if in fact these hoses were already cleaned and disinfected. After the employee affirmed the information to Mrs. Dillon, she asked him if he was willing to re-clean it and sanitize again. The employee took the hoses to the cleaning room dedicated to these purposes.

On 03/12/2018 I observed a jacket stored next to filling line (b) (4) while (b) (4) Black Shampoo + Conditioner Lot# 18J0308039 was being processed in this line. After I pointed it out to Mrs. Dillon, she found the employee and asked him to remove it and store it in the designated area.

On 03/19/2018 I observed empty containers of (b) (4) Rejuvabeads left uncovered and exposed in filling line (b) (4) after the employees left for the day. I pointed this situation out to Mrs. Dillon and she brought 2 employees that placed all the containers back in their cases.

EXHIBITS COLLECTED

1(MF) EX 1 Organizational Chart - 1 page
2(MF) EX 2 Reconciliaton Exam EQ-19 - 2 pages
3(MF) EX 3 EQ-19 Bill of Lading - 4 pages
4(MF) EX 4 VIP ME - 12 pages
5(MF) EX 5 We Are Modern Nature - 30 pages
6(MF) EX 6 Direct Selling News - 20 pages
7(MF) EX 7 (b) (4) Product List - 2 pages
8(MF) EX 8 Top 5 (b) (4) Shampoos and Conditioners - 1 page
9(MF) EX 9 (b) (4) containers with imprint labels - 14 pages
10(MF) EX 10 Facility Diagram (Manufacturing building) - 1 page
11(MF) EX 11 SOP Weighing Procedure - 2 pages
12(MF) EX 12 SOP Batching Procedure - 2 pages

13(MF) EX 13 SOP Cleaning and Sanitization Manufacturing Equipment - 6 pages
14(MF) EX 14 Manufacturing Tanks Holding Tanks Totes Cleaning and Sanitization Work Instructions - 1 page
15(MF) EX 15 Cleaning Log Reactor (b) (4) - 1 page
16(MF) EX 16 (b) (4) Water System Test - 1page
17(MF) EX 17 SOP Pest Control Program - pages
18(MF) EX 18 Cola Det EQ-19 Information Sheet - 3 Pages
19(MF) EX 19 Cola Det EQ-20 Information Sheet - 3 Pages
20(MF) EX 20 Raw Material Information - 8 pages
21(MF) EX 21 Challenge Study (b) (4) Renew Balance Shampoo - 6 pages
22(MF) EX 22 Challenge Study (b) (4) Black Shampoo + Conditioner - 6 pages
23(MF) EX 23 Challenge Study (b) (4) Revive Shampoo - 6 pages
24(MF) EX 24 Finished Product Log book - 26 pages
25(MF) EX 25 (b) (4) Hair Damage Testing - 30 pages
26(MF) EX 26 Damage Reduction Test - 42 pages
27(MF) EX 27 Hair Combability Test - 28 pages
28(MF) EX 28 Evaluation of Tensile Properties Test - 60 pages
29(MF) EX 29 (b) (4) Black Shampoo + Conditioner Safety Assessment - 304 pages
30(MF) EX 30 Product Safety Assessments DV-R - 2 pages
31(MF) EX 31 Color Additives Certifications - 5 pages
32(MF) EX 32 (b) (4) SOP Complaints - 5 pages
33(MF) EX 33 (b) (4) Complaint forms - 3 pages
34(MF) EX 34 SOP Complaints - 3 pages
35(MF) EX 35 Complaints Log book - 4 pages
36(MF) EX 36 SOP Product Recall Procedure - 11 pages
37(MF) EX 37 Copies of 29 Photos - 15 pages
38(MF) EX 38 DV-R with negative images (Originals and Copies) - 4 pages
39(MF) EX 39 (b) (4) Clinical Studies (from the web) - 18 pages

ATTACHMENTS
1(MF) Issued 483
2(MF) Amendment 1
3(MF) Amendment 1
4(MF) Amendment 1
5(MF) Amendment 1
6(MF) Amendment 1
7(MF) ATT 2 Form FDA 482 Notice of Inspection - 6 pages

X Marinee Flores-Marrero
Investigator
Signed By: Marinee Flores-marrero -S
Date Signed: 06-05-2018 11:09:55

X Goran Periz -S
Digitally signed by Goran Periz -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Goran Periz -S, 0.9.2342.19200300.100.1.1=0011327398
Date: 2018.06.05 12:10:45 -04'00'