

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	DATE(S) OF INSPECTION 3/12/2018-3/20/2018* FEI NUMBER 3003505078
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Maria Castellon, President

FIRM NAME B and R Products, Inc.	STREET ADDRESS 18721 SW 104th Ave
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CITY, STATE, ZIP CODE, COUNTRY Cutler Bay, FL 33157-6832	TYPE ESTABLISHMENT INSPECTED Cosmetics Manufacturer
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This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
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# 18J0308038 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 (b) (4) 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# 18J0308039 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.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Marinee Flores-Marrero, Investigator Goran Periz, FDA Center Employee or Employee of Other Federal Agencies	Marinee Flores-Marrero Investigator Signed By: Marinee Flores- marrero-S Date Signed: 04-02-2018 11:20:07 X	DATE ISSUED 4/2/2018

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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.

***DATES OF INSPECTION**
3/12/2018(Mon), 3/13/2018(Tue), 3/14/2018(Wed), 3/16/2018(Fri), 3/19/2018(Mon), 3/20/2018(Tue)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Marinee Flores-Marrero, Investigator Goran Periz, FDA Center Employee or Employee of Other Federal Agencies	Marinee Flores-Marrero Investigator Signed By: Marinee Flores- marrero-S Date Signed: 04-02-2018 11:20:07 X _____	DATE ISSUED 4/2/2018