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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 12420 Parklawn Drive, Room 2032<br>Rockville, MD 20857 | 06/17/2024-06/21/2024 |
| | FEI NUMBER<br>3007389902 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Reva A. Kohn, Chief Financial Officer

| FIRM NAME | STREET ADDRESS |
|---|---|
| Brands International Corporation | 594 Newpark Blvd |
| CITY, STATE, ZIP CODE, COUNTRY<br>Newmarket, L3X 2S2, Canada | TYPE ESTABLISHMENT INSPECTED<br>OTC Drug Manufacturer |

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

**The quality control unit lacks the responsibility and authority to approve or reject, all components, drug product containers, closures, in process materials, packaging material, labeling, and drug products.**
**Specifically,**

(A) Your quality unit failed to exercise its responsibility to ensure drug products manufactured at your facility have the safety, identity, strength, quality, and purity that it purports or is represented to possesses. Discrepancies were not adequately investigated, and incorrect and misleading information was provided during the inspection causing unnecessary delays.

For example,

On 6/17/2024, we requested your firm to all provide customer complaints submitted to your facility since the last inspection. Your firm, however only provided a list of seven (7) complaints for 2024 and stated you were unable to find other complaint records for your company. However, on 06/20/2024, different information was identified that contradicted the original information related to your complaints. During a walkthrough of your laboratory, we identified positive mold growth samples for your [redacted] (b) (4) lotion Batches [redacted] (b) (4) stored underneath boxes in your QC laboratory office. We were informed by your staff that the samples were for retain batches, which were tested due to a customer complaint for mold in your products. However, your facility failed to disclose this complaint and the positive growth samples during the inspection.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE *(Print or Type)* | DATE ISSUED |
|---|---|---|---|
| | | Crystal Monroy, Investigator<br>Jose E Melendez, DDC Investigator | June 21, 2024 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
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(B) Your Quality Unit has failed to ensure that all production and laboratory control operations are CGMP adopted. All the deficiencies found during current FDA inspection are indicative that your Quality Unit has not taken the necessary steps to fully ensure the adequacy of your procedures, analytical methods, and tests results and that complaints reported are appropriately investigated. Furthermore, the Quality Unit has not performed the necessary assessments/reviews to ensure that the objectionable practices observed do not negatively affect the quality attributes of your over-the-counter (OTC) drug products. The objectionable conditions noted below suggest that personnel may not have the necessary skill sets/training, experience and/or scientific knowledge with respect to drug manufacturing processes and related systems in order to adequately assess the CGMPs. Moreover, many of the objectionable conditions noted below document that personnel may not have the necessary understanding about the importance of ensuring the integrity of the CGMP data.

(C) Responsibilities and procedures applicable to the quality unit are not fully in writing or have been changed by your facility and there are no written procedures describing your firm's current practices. Procedures not followed include but are not limited to:

- Complaints
- Corrective action and preventative action
- Batch record review
- Stability
- Change management
- Documentation control policy
- Quarantine
- Product returns
- Retain samples
- Annual product review
- Training

(D) Your quality unit has failed to maintain records related to CGMP regulated operations and activities at your establishment. This includes but is not limited to records related complaints, training, QC

laboratory records, and batch production records. Your firm does not have a records control system in place and records are stored in various locations in your facility. There is no designated area for records storage and traceability.

**OBSERVATION 2**

**Investigations of an unexplained discrepancy, or a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product or other drug products that may have been associated with the specific failure or discrepancy.**

Specifically,

On June 7, 2024, your firm received a customer complaint for (b) (4) (b) (4) Lotion, Batch (b) (4) and initiated a Corrective Actions and Preventive Actions assessment as your investigation. However, your firm failed to conduct an adequate and thorough investigation due to the following:

(1) Your investigation did not follow your firm's complaint investigation handling procedures per SOP QA-LS) P009 Rev 1 effective 11/05/2021.

(2) Your complaint was investigated as a Corrective Action and Preventative Action (CAPA) and not as an investigation. No documentation or data was captured in your CAPA defining the investigation that was performed.

(3) Your CAPA states that (b) (4) retain batches were inspected but only two (2) were affected. Your CAPA does not explain how the retain batches were inspected and there is no documented evidence confirming such evaluation.

(4) Your onsite quality laboratory confirmed [redacted] (b) (4) Lotion, Batches [redacted] (b) (4) and [redacted] (b) (4) were positive for mold; however, no laboratory investigation was performed/documented/approved.

(5) Your CAPA report concludes the root cause for the mold contamination to be the components (pumps); however, there is no documentation or data supporting the root cause. According to your Site Quality Manager, the pump was received contaminated from the supplier. Nonetheless, no complaint was filed against the supplier, as the pumps were received a long time ago and traceability of this component was lost.

(6) Your CAPA investigation report has failed to extend to other batches of OTC products that utilize the affected pump. Your Quality Unit currently does not have a system in place to trace the components used for your OTC drug products.

(7) Although your laboratory investigation confirmed [redacted] (b) (4) lotion Batches [redacted] (b) (4) and [redacted] (b) (4) you have failed to implement an immediate corrective action.

## OBSERVATION 3

**Your firm failed to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release.**

Your Quality Unit failed to exercise its responsibility to ensure the OTC products manufactured at your facility are in compliance with CGMP and meet established specifications for quality and purity. Specifically, [redacted] (b) (4) Cream OTC drug product, Batch [redacted] (b) (4) was released on [redacted] (b) (4) [redacted] (b) (4) without assay testing for [redacted] (b) (4) content, which is the main active ingredient in the formulation. Additionally, your QC laboratory has never tested incoming batches of [redacted] (b) (4) raw materials. Your firm has been manufacturing this product since [redacted] (b) (4)

## OBSERVATION 4

**Batch production and control records do not include complete information relating to the production and control of each batch.**

Your batch records do not include accurate data derived from in-process testing to assure compliance with established specifications.

(A) In-process weighing test for units of [(b) (4)] Cream OTC product, Batch [(b) (4)] is not accurate. On June 17, 2024, we observed the filling process of Batch [(b) (4)] The in-process weighing test of filled units should be monitored [(b) (4)] During this monitoring, [(b) (4)] units are removed from the filling machine. We observed that the Quality Unit did not collect the samples for the monitoring at [(b) (4)] and [(b) (4)] At approximately [(b) (4)] the Quality Unit removed the [(b) (4)] filled units from the conveyor and weighed them individually. However, these weight results were not documented in the batch record. After a while, we observed the Quality Unit randomly documented the [(b) (4)] weight results in the batch record. This deficiency was discussed with the Site Quality Manager. However, no process deviation was initiated, and no corrective actions were implemented.

(B) Your firm failed to document in the manufacturing batch records critical process controls such as, [(b) (4)] used to monitor the manufacturing process of your OTC products (e.g., [(b) (4)] Cream, [(b) (4)] Cream and [(b) (4)] Shampoo) distributed in the USA market. Therefore, there is no assurance that the established manufacturing process was followed at the time of performance.

## OBSERVATION 5

**Individuals responsible for supervising the manufacture, processing, packing, or holding of a drug product lack the education, training, and experience to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.**

Specifically,

(A) Your Quality Unit consists of (b) (4) new personnel responsible for overseeing the quality functions of your establishment. However, the current staffing under the quality unit lacks the resources, education, and training to support the current quality functions at your establishment.

(B) The individuals responsible for supervising the manufacture, processing, packing, holding, and release of your OTC drug products are not aware of CGMP regulations and their implementation and are not following the guidelines to assure the drug product has the safety, identity, strength, quality, and purity that it purports to possess.

## OBSERVATION 6

**There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.**

Your firm failed to conduct process validation for your commercial OTC products distributed in the USA market. For example, your firm did not provide documented evidence to demonstrate that the manufacturing processes of (e.g., (b) (4) cream, (b) (4) soap, (b) (4) (b) (4) shampoo, and (b) (4) Cream) are reproducible and controlled to consistently produce batches within expected quality attributes. You also have not conducted equipment qualification.

**OBSERVATION 7**

**Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.**

You have not conducted cleaning validation studies to demonstrate that your cleaning procedures for non-dedicated production equipment (e.g., (b) (4) tanks, holding tanks and filling lines) are adequate to prevent potential cross-contamination between the OTC drug products (e.g., cream and ointments) manufactured at your facility.

**OBSERVATION 8**

**Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.**

Your firm failed to validate the microbiological rapid test used as part of the release testing of your OTC products. There is no documented evidence on the criteria of your current test method to detect, identify, and quantify all microorganisms that may now be, or have the potential to be associated with your commercial OTC drug products.

**OBSERVATION 9**

**The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established.**

Analytical test methods that you used to determine acceptability of your drug products prior to release for distribution are not validated or verified, for USP compendial methods. These methods include, but are not limited to, assay, limit of preservative, and specific gravity.

For example, there is a lack of validating analytical methods for the determination of [redacted] (b) (4) which are the main ingredients in the formulations of your over-the-counter [redacted] (b) (4) Soap and [redacted] (b) (4) products distributed in the US market. A review of laboratory records found that your QC laboratory has been releasing in-coming materials and finished products of subject OTC products, and no analytical method validation activities have conducted.

**OBSERVATION 10**

**Representative samples are not taken of each shipment of each lot of drug product containers for testing or examination.**

There is no assurance that your current sampling plan is scientifically sound and leads to representative samples of in-coming raw materials.

(A) There is no documented evidence that your in-coming sampling for [redacted] (b) (4) raw materials, which are the main ingredients in the formulations of [redacted] (b) (4) and [redacted] (b) (4) soap is representative of the shipment received. There is no evidence regarding the number of containers sampled or the amount of raw materials sampled from each container to demonstrates that incoming raw materials are evaluated based on statistical criteria.

(B) Your QC laboratory failed to perform assay testing for in-coming batches of [redacted] (b) (4) raw materials, which are identified as main ingredients in the formulations of [redacted] (b) (4) Cream, [redacted] (b) (4) Cream and [redacted] (b) (4) Shampoo OTC products. The results of these assay testing have always been taken from the suppliers' Certificate of Analysis (COA).

(C) Your Quality Control laboratory did not provide limit test results for [redacted] (b) (4) for batches of [redacted] (b) (4) USP.

Specifically, your firm received batches of [redacted] (b) (4) USP raw material, Batches [redacted] (b) (4) and [redacted] (b) (4) but there is no documented evidence that these lots were tested for [redacted] (b) (4) limits before use in manufacturing of your OTC products.

**OBSERVATION 11**

**There is a failure to handle and store components, drug product containers, and closures at all times in a manner to prevent contamination.**

**Specifically,**

(A) During the walkthrough of your facility on 06/17/2024 the following deficiencies were observed:

(1) Several doors in your warehouse had gaps that are large enough to allow pests to enter your facility. Your warehouse consists of approximately [redacted] (b) (4) doors directly facing the outside of your facility and several of the doors had gaps on the floor and faced the outside of your facility. In addition, we identified at least one [redacted] (b) (4) door that had an opening on the top of the door that was large enough to allow pest to enter the facility.

(2) We observed approximately [redacted] (b) (4) shipping trucks that contained various inventory, including components and finished drug products. The items on the trucks were in an unkept state with inventory piled on top of each other, fallen over, or covered with dirt and filth. Your warehouse manager stated that some of the trucks are used as an extension of the warehouse. The temperature that day was approximately 33 °C (92 °F). Additionally, he mentioned that the inventory in some of the trucks is to be destroyed; however, you do not have an inventory of the items in these trucks and their disposition status.

(3) Your warehouse is in an unkept state. We observed components stored in boxes inside the warehouse had signs of apparent damage including water damage and several torn boxes exposing the components prior to use.

(4) The outside of your facility is in an unkept state. We observed numerous items on the floor outside of your facility including components (pumps) on the ground, manufacturing equipment, raw materials, and standing water.

(B) Your firm's pest control program is deficient. From January 2024 to May 2024 your firm has received pest control reports by a third-party company who services your facility. The reports show rodent infestation at various areas in your facility. Your establishment is not ensuring adequate actions are being taken to manage/control the infestation in your facility.

**OBSERVATION 12**

**The written stability testing program is not followed.**

Your Quality Unit failed to conduct a long-term room temperature stability study to support the expiration dates of your over-the-counter drug products.

Specifically, there is a failure to design and establish an ongoing stability program for OTC commercial products (e.g., (b) (4) Cream, (b) (4) Soap, (b) (4) Shampoo and (b) (4) Cream) distributed in USA market.

Your Quality Unit assigns an expiration date of (b) (4) depending on the product formulation. However, there is no scientific evidence or data to demonstrates that current manufacturing process/controls will produce OTC products that will remain within their quality attributes throughout the entire expiration date, as commercial products that represent annual production lots are not subject to an ongoing stability program.

**OBSERVATION 13**

**Procedures designed to assure conformance to written specifications do not require appropriate retesting of components, drug product containers, and closures subject to deterioration. Specifically,**

Your firm has been manufacturing [redacted] (b) (4) soap using an active ingredient that is beyond the retest date. [redacted] (b) (4) Batch [redacted] (b) (4) is the active ingredient for your OTC [redacted] (b) (4) soap. Your firm has been using this batch which has been in your inventory. Upon review of the raw material in your warehouse, it was observed, the raw material has been expired since 2023-04-24 and has not been retested. After this discrepancy was discussed with your Site Quality Manager, your staff stated they were not aware and contacted the supplier for a revised COA confirming retesting. However, you failed to provide the in-house retesting results to confirm the results reported in the COAs. Furthermore, you have been using [redacted] (b) (4) Batch [redacted] (b) (4) to manufacture approximately [redacted] (b) (4) different types of [redacted] (b) (4) soap since April 2023 to June 2024.

**OBSERVATION 14**

**Written procedures describing the handling of complaints do not include provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications and a determination as to the need for an investigation of any unexplained discrepancy.**

Your firm's complaint handling practices are deficient. For example:

(A) Your complaint intake process is inadequate. According to your QA supervisor, your firm receives complaints by your clients and completes form QA-LFO017-R0 for Customer Complaint Form. Your form is deficient in that it does not require information regarding firm personnel who received and recorded the complaints. Furthermore, your complaint intake process is not always being followed (Refer to FDA Observation 2).

(B) Complaints received are not thoroughly investigated to establish if complaint may be tied to quality issue. For example, Complaint C 03/2024 received January 11, 2024, was for particle issues in drug product [redacted] (b) (4) Soap. According to your complaint summary, the customer indicated there was an issue with [redacted] (b) (4) particles, resembling [redacted] (b) (4) ' inside the product. Your QA supervisor stated she contacted the customer who provided the product

manufacturing date and expiration dates. Your firm did not perform a review to identify the (b) (4) (b) (4) manufacturing batch received by your customer and failed to initiate an investigation on your product to establish if the complaint may be tied to a quality issue. Your investigation only states the customer was provided a "replacement" and "a gift" as a resolution to this complaint investigation.

## OBSERVATION 15

**Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices, and written procedures required by good manufacturing regulations.**

Your (b) (4) CGMP training program for all employees is not being followed. SOP AQ-LSOP011, GMP Training Standard Operating Procedure, Revision 1, effective 11/05/2021, requires a (b) (4) GMP refresher training at your site. However, your firm does not have records demonstrating (b) (4) CGMP training has been performed for all employees, including part time employees and upper management, at your facility. Furthermore, your cGMP training procedure lacks specificity on the CGMP principles employees are trained on.

## OBSERVATION 16

**The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, drug product containers, closures, and drug products and to prevent contamination.**

Your firm does not have an adequate warehouse for the proper management and storage of components, drug product containers, and closures, raw materials, and finished product.

For example:

(A) You do not have a warehouse inventory management system. Your warehouse inventory is held throughout the warehouse and there is no system in place to facilitate in identifying the status of your materials (e.g. approved, rejected, released), quantities remaining, and location of items in warehouse.

(B) Items are intermingled in your warehouse. Although your firm has identified designated locations for material storage in the warehouse including but not limited to released finished products, quarantine, or rejected, these designated areas are not being followed. During the walkthrough of your facility on 06/17/2024 and 06/19/2024, we observed material stored throughout your facility in areas designated for quarantine or rejection, on the aisle of the warehouse, and piled on top of each other.

(C) Rejected and returned materials are stored in shipping trucks connected to your facility. The storage conditions inside these trucks are deficient and you do not have records of the current inventory of items in the rejection and returned trucks.

## OBSERVATION 17

**Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.**

Your firm's annual product review (APR) is deficient and is not being performed for all your USA marketed OTC products.

(A) Your firm has failed to perform annual product review for all the OTC products manufactured at your facility. This includes but is not limited to the following:

(b) (4)

[redacted] (b) (4)

(B) In 2022, your firm performed an APR for the following OTC products: [redacted] (b) (4) Soap, [redacted] (b) (4) Soap, [redacted] (b) (4) Soap, [redacted] (b) (4) Soap, [redacted] (b) (4) Cream. The following deficiencies were identified in the APRs:

(1) Your APRs do not define batches manufactured for product during the year being reviewed.

(2) The APR lacks specificity and focuses on an assessment of applicable procedures to your product. There is no documented evidence either about the number of rejected batches, complaint investigations, recalls, returned batches or manufacturing/laboratory investigations that occurred during the year being reviewed.

## OBSERVATION 18

**Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.**

Your firm has failed to maintain an adequate reserve sample program for all the OTC drug products manufactured at your facility.

For example:

(A) You do not keep retain samples of all the products manufactured at your facility. During the inspection, your firm was unable to identify retain samples for the following products manufactured:

- [redacted] Shampoo lot [redacted]
- [redacted] Shampoo lot [redacted]
- [redacted] Soap Lot [redacted]
- [redacted] lot [redacted]

(B) Your retention sample inventory management is inadequate. You rely on a retention sample form to document the samples collected for [redacted] however, you do not document the storage location, and do not always document complete lot numbers for traceability of your samples.

(C) The conditions of your retention sample room are deficient. Retain samples are placed in bags inside cardboard boxes that are stored on shelves. The boxes in the retains room are unorganized and there no method to trace the location of retains in your establishment. Furthermore, the temperature of the room is high and although, temperature is monitored [redacted] it is not monitored during highest temperature [redacted] to ensure the samples are maintained in adequate temperature conditions. You have not conducted a mapping study of the retain room. There is only one temperature probe monitoring the room temperature.

(D) Your firm does not perform an annual review of retention samples and does not document instances when retains are used to conduct investigation. For example, retention samples for [redacted] lotion, Batches [redacted] and [redacted] were collected for testing; however, you do not have a control procedure to document when retains are taken and returned.

## OBSERVATION 19

**Established laboratory control mechanisms are not documented at the time of performance.**

Your QC analysts failed to document the raw data of your in-coming/release testing. For example, your analysts do not document the sample/standard preparations, the solvents/reagents used during the analysis, including the lot numbers, the preparation of the mobile phase and the lot number of the

reference standard used in the preparation and testing of your chemical analysis (i.e. HPLC and GC). Therefore, there is no assurance that established analytical procedures were consistently followed during OTC product testing.