DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	4/22/2024-4/30/2024*
	FEI NUMBER 3014583374

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Keith Burk, CEO

FIRM NAME	STREET ADDRESS
Avaria Health & Beauty Corp.	5-650 Jamieson Pky
CITY, STATE, ZIP CODE, COUNTRY Cambridge, Ontario, N3C 0A5	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that conform to appropriate standards of identity, strength, quality and purity.

Specifically,

The quality control unit fails to ensure that the raw material, (b) (4) used for the manufacturing of OTC drug products shipped to the U.S. has safety limits of (b) (4) contamination.

OBSERVATION 2

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically,

The quality control unit fails to ensure that at least one test is performed to verify the identity of the following incoming raw materials used for the manufacturing of OTC drug products shipped to the U.S.

(b) (4)

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(b) (4)

OBSERVATION 3

Verification of the suitability of the testing methods is deficient in that they are not performed under actual conditions of use.

Specifically,

The quality control unit failed to ensure that the analytical test method used for the quantification of (b) (4) contamination in (b) (4) used in manufacturing drug products is verified under actual conditions of testing. Without (b) (4) hod verification there is no assurance that the (b) (4) test results are accurate, precise, and reliable.

OBSERVATION 4

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

The firm failed to validate the manufacturing process and equipment that are used to manufacture the following OTC drug products for the U.S. market.

(b) (4)

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OBSERVATION 5

The quality control unit lacks the responsibility and authority to approve and reject all components.

Specifically,

The quality control unit failed to ensure that the Raw Material Specification for the (b) (4) of drug products (document No (b) (4) version (b) (4) effective date (b) (4) does not depict misleading information regarding to the Microbial Limit Test (i.e., Total Plate Count and Yeast and Mold) making erroneously reference to the USP when in reality, the test is an In-house test.

OBSERVATION 6

Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

The quality control unit fails to establish a calibration program for the following electronic devices used to support the manufacturing and release of OTC drug products:

a. Temperature and humidity devices used to monitor the environmental conditions of the: accelerated stability chamber, long term stability area, compounding area, and retain storage area.
b. (b) (4) pH meter used to monitor and report the pH of the (b) (4) used for the manufacturing of OTC drug products.
c. (b) (4) conductivity meter used to monitor and report the conductivity of the (b) (4) used for the

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manufacturing of OTC drug products.

d. (b) (4) (b) (4) device used to report Microbial Limit of Water.

OBSERVATION 7

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.

Specifically,

The quality control unit fails to establish annual product reviews for OTC drug products.

OBSERVATION 8

The number of containers to be sampled is not based upon appropriate criteria.

Specifically,

The quality control unit fails to establish an appropriate sampling criteria such as statistical criteria for component variability, confidence levels, degree of precision required, past quality history of supplier, quantity needed for analysis and reserve of in-coming raw materials and active ingredients. For example,

a. On 07/22/2022, the firm received (b) (4) drums ((b) (4) kg each) of the raw material, (b) (4) USP, lot (b) (4) from where (b) (4) drum was sampled without a sampling m d criteria. Additionally, the quality control unit failed to record the amount of sample taken and the drum sampled.

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b. Standard Operating Procedure AQSP-MTRL-01, Raw Material Receiving, Sampling, Testing, Approval, Storage, and Disposition, revision 00, effective date 01/03/2023 is deficient establishing a sampling method and criteria.

***DATES OF INSPECTION**

4/22/2024(Mon), 4/23/2024(Tue), 4/24/2024(Wed), 4/25/2024(Thu), 4/26/2024(Fri), 4/29/2024(Mon), 4/30/2024(Tue)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."