DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food & Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	07/15/2025 to 07/21/2025* FEI NUMBER 3024609429

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Joseph Mizikovsky, CEO	
FIRM NAME Veganic SKN Limited	STREET ADDRESS 81 Shettleston Street Unit III
CITY, STATE, ZIP CODE, COUNTRY Rocklea, Queensland, Australia, 4106	TYPE ESTABLISHMENT INSPECTED Finished Product 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

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically,

Your firm has not established written procedures defining the quality control unit's responsibilities and authority. Standard operating procedures describing the quality control unit's role and scope of authority were not available during the inspection. As a result, personnel were unclear about their specific duties and decision-making responsibilities within the quality control function.

OBSERVATION 2

The quality control unit lacks the responsibility and authority to approve, reject all drug products.

Specifically,

a) Manufacturing operations are currently proceeding without qualified Quality Assurance (QA) oversight present during critical process steps. This deficiency includes a lack of real-time review and approval of critical process parameters and deviations by qualified QA personnel. Additionally, there is insufficient QA involvement in batch record review during active

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production phases. The facility's current practice involves production employees fulfilling QA responsibilities, as confirmed by your Head of QA during our inspection. This arrangement compromises the independence required for effective quality oversight, as production personnel cannot provide the objective review necessary for proper QA functions. From 06/02/2024 to 05/05/2025, your firm released (b) (4) lots of (b) (4) products to the US market. A specific example of this deficiency is observed with Lot# (b) (4) which demonstrates inadequate QA oversight throughout critical process steps. Moreover, this lot was released for distribution without receiving final QA approval. As another example, I observed that Lot #(b) (4) was released by your production manager on behalf of QA.

b) Your firm released Lot #(b) (4) with an open Out of Specification (OOS) investigation. Your contract testing laboratory (b) (4) who is responsible for testing the finished (b) (4) products, reported an OOS result for (b) (4) on 08/28/2024. The reported result was (b) (4) for a specification of "(b) (4) ". (b) (4) opened an investigation # OOS No: 276B on 08/28/2024, and Phase II of the investigation was initiated on 12/04/2024; however, the investigation was not completed until 07/11/2025. Your firm released this lot on (b) (4) and shipped it to the US market on (b) (4)

c) From 06/02/2024 to 05/05/2025 your firm released (b) (4) lots of (b) (4) products to the US market without receiving the test results from your contract testing laboratory, (b) (4) For example, Lot # (b) (4) was released and shipped to US market by your firm on (b) (4) however, the Certificate of Analysis was not issued by (b) (4) until 05/14/2025, more than (b) (4) after product release.

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OBSERVATION 3

Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, drug product closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.

Specifically,

From 06/02/2024 to 05/05/2025, your firm released (b) (4) lots of (b) (4) products to the US market without conducting required microbiological testing, including testing for (b) (4) (b) (4) All your (b) (4) products contain (b) (4) an inactive ingredient in the formulations, which significantly increases the microbiological risk profile and necessitates comprehensive microbiological testing to ensure product safety.

OBSERVATION 4

Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis.

Specifically,

From 06/02/2024 to 05/05/2025 your firm released (b) (4) lots of (b) (4) products to the US market. These lots were manufactured using (b) (4) as an inactive ingredient. At the time of manufacturing, you accepted the (b) (4) based on the supplier's Certificate of Analysis (COA) and failed to conduct specific identity analysis for each lot, which should include a limit test for (b) (4) and incorporates testing of samples from all containers of all lots. For example, (b) (4) Lot # (b) (4)

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(b) (4) was manufactured using (b) (4) lot # (b) (4) which was accepted based on the supplier's COA.

OBSERVATION 5

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,

Your firm currently assigns expiration dates based on the packaging date of (b) (4) products rather than the compounding date, which fails to account for the actual age of the bulk product and potential degradation during storage. Your firm proposes a (b) (4) expiry period from packaging. For example, (b) (4) lot # (b) (4) was compounded on (b) (4) but not packaged until (b) (4) (approximately (b) (4) later), yet was assigned an expiration date of (b) (4) effectively giving it nearly (b) (4) total shelf life from compounding

OBSERVATION 6

Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed.

Specifically,

From 06/02/2024 to 05/05/2025 your firm released (b) (4) lots of (b) (4) products to the US market without conducting adequate hold time study. Following are examples of lots released without adequate hold time studies:

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Batch No	Bulk ID	Bulk Man. Date	Manufacturing Date of The Product (b) (4)
(b) (4)			

*** DATES OF INSPECTION**
07/15/2025 (Tue), 07/16/2025 (Wed), 07/17/2025 (Thu) and 07/18/2025 (Fri) and 07/21/2025 (Mon)

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