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	3/31/2025-4/8/2025*
	FEI NUMBER 3007187387

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Valentine P. Fittler, CEO & Managing Director

FIRM NAME	STREET ADDRESS
Cosmetic Manufacturers (Aust) Pty Ltd.	U 3-14 Kingston Dr
CITY, STATE, ZIP CODE, COUNTRY Helensvale, Queensland, 4212 Australia	TYPE ESTABLISHMENT INSPECTED Manufactuer

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

Your firm failed to establish adequate 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,

A. Your firm has not conducted any protocol driven Packaging Process Validation Studies, in particular product-specific filling validation studies with pre-approved acceptance criteria. The following are some examples of drug products that lack protocol-based packaging process validation studies:

(b) (4)

B. There were no bulk hold time studies performed for to support the bulk drug product hold times for the drug products, (b) (4) According to the batch records titled, "Master Batch Documentation: (b) (4) MM008/14 and "Master Batch Record: (b) (4) MM002/20, the bulk hold times are (b) (4) respectively.

C. The (b) (4) system was not sampled at a high sampling frequency during the initial phase of the qualification to detect short-term and/or localized chemical or microbial quality deviations from all points of use/outlets. Per the (b) (4) system qualification protocol titled "Installation & Operational Qualification: (b) (4) System" No. VAL 02, dated: 11/05/2005, the (b) (4) system was qualified retrospectively

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following its installation and placement into operation, and the previous 12 months of (b) (4) testing data from the manufacture room # (b) (4) and manufacture room # (b) (4) were used. The (b) (4) locations within the production rooms, manufacture room # and manufacture room # were sampled and tested (b) (4) for (b) (4) and (b) (4) for (b) (4) which is the normal operational sampling schedule.

D. The Quality Unit does not test the drug products produced, (b) (4) (b) (4) for assay and related substances prior to their release during the bulk product testing or following final drug product packaging. Testing is only performed for bioburden prior to release.

E. The production process validation of (b) (4) titled "Process Validation: MM008 (b) (4) Bulk" VAL 099, rev 00, did not ensure the full dissolution of the components through verification, by adequate sampling that accounts for location effects. The suspension was sampled in only the (b) (4) of the tank and was not tested for assay.

OBSERVATION 2

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

A. Your firm failed to perform a representative equipment qualification, specifically the Operational Qualification (OQ) and the Performance Qualification (PQ) studies for the (b) (4) Filler Machine, which is utilized in the manufacture (b) (4) The equipment was run by (b) (4) In total the filling machine was run for only (b) (4) units in liquid-based product fillings and failed to demonstrate that the filling machine can operate as intended in "Packaging Work Order, MM008B-US: (b) (4) US (M0399)," for the commercial scale filling batch size of approximately (b) (4) units.

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B. Your firm failed to perform representative equipment qualifications, specifically the Operational (OQ) and the Performance Qualification (PQ) studies for the (b) (4) which is utilized in the manufacture of (b) (4) In the IQ/OQ studies you performed for this (b) (4) titled, "Installation & Operational Qualification (b) (4) (b) (4) were run by accessing data of previously run batches of cosmetic products and failed to demonstrate that the unit can operate as expected for (b) (4) °C for a minimum of (b) (4) as identified in "Master Batch Documentation: Bulk- (b) (4) and "Master Batch Documentation (b) (4)

C. The appropriate quality of (b) (4) is not utilized in the cleaning of production equipment for the drug products, (b) (4) According to the procedures titled "(b) (4) Operation, Assembly and Cleaning" SOP 0449, "(b) (4) Filler-Disassembly and Cleaning" SOP 0411, and "Cleaning of Manufacturing Tanks" SOP 0405, the production and filling equipment are (b) (4) and a (b) (4) is not performed.

D. Your firm failed to provide worst-case sampling location assessments of shared GMP equipment for your equipment cleaning validation study protocol titled "Cleaning Validation" VAL 017. The shared equipment is utilized for the production, filling, and packaging of (b) (4) The cleaning validation swab samples were not taken consistently from the worst-case locations specific to each shared part, and comparative data to assess the cleaning process was not obtained.

OBSERVATION 3

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

Specifically,

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A. Suitability studies demonstrating that drug product formulations do not inhibit microbial growth were not performed on the bioburden tests performed according to "Product Specification: Product Name (b) (4) (b) (4) " SOP 0258, Attachment E and "Product Specification: Product Name (b) (4) (b) (4) SOP 0258, Attachment E.

B. (b) (4) which is a component of (b) (4) drug products, (b) (4) (b) (4) is not monitored and tested for (b) (4) (b) (4) The (b) (4) specifications titled '(b) (4) RMS- WAA indicate for the testing of appearance, conductivity, bioburden (i.e., TAMC and TYMC), *Pseudomonas*, oxidizable substances, and (b) (4)

C. (b) (4) which is a component of (b) (4) (b) (4) is not sampled and tested on production days. According to the procedure titled "(b) (4) Quality Manual" SOP 0307, (b) (4) is sampled and tested (b) (4) (b) (4) and (b) (4) is sampled and tested (b) (4) in manufacture room (b) (4) and manufacture room (b) (4) Manufacture room (b) (4) is the production location for (b) (4) (b) (4)

OBSERVATION 4

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm failed to initiate a non-conformance investigation following yield failures at various phases of processing during the production, filling, and packaging of drug products. Per the "Quality Manual" QM, rev 04, the Quality Unit is responsible for reviewing batch records to "ensure…that reconciliations and yields have been calculated and are within specifications. Additionally, the QM rev 04 indicates that the Quality unit is to investigate and report "any deviations or non-conformances that occurred during production or testing." The following are yield discrepancies that transpired during the production, filling, and/or packaging of (b) (4) (b) (4) but did not

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have subsequent non-conformance investigations initiated by the Quality Unit:

1) (b) (4) lot (b) (4) (bulk lot (b) (4)
The bulk yield was not in specification for the batch. The "expected yield" for the drug product according to the "Master Batch Documentation: Bulk- (b) (4) MM002/18 is (b) (4) (b) (4) and the actual yield was reported as (b) (4) on 11/20/2023.

2) (b) (4) lot (b) (4) (bulk lot (b) (4)
The bulk yield was not within specification for the batch. The "expected yield" for the drug product according to the "Master Batch Documentation: Bulk- (b) (4) " MM002/18 is (b) (4) and the actual yield was reported as (b) (4) on 05/27/2024.

3) (b) (4) lot (b) (4) bulk lot (b) (4)
The final drug product yield following filling and packaging was not within specification for the batch. The "% yield" for the drug product should be NLT (b) (4) % according to packaging batch record titled "Packaging Work Order: Product: (b) (4) US (M0399), and the actual yield was (b) (4) %.

4) (b) (4) lot (b) (4) (bulk lot (b) (4)
The final drug product yield following filling and packaging was not within specification for the batch. The "% yield" for the drug product should be NLT (b) (4) % according to packaging batch record titled "Packaging Work Order: Product: (b) (4) US (M0399), and the actual yield was (b) (4) %.

***DATES OF INSPECTION**
3/31/2025(Mon), 4/01/2025(Tue), 4/02/2025(Wed), 4/03/2025(Thu), 4/04/2025(Fri), 4/07/2025(Mon), 4/08/2025(Tue)

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