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	10/23/2023-10/27/2023
	FEI NUMBER 3010970108

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeong-seok Yang, Associate Executive

FIRM NAME	STREET ADDRESS
First Cham Co., Ltd.	87 Geumillo700beon-Gil, Samseong-Myeon
CITY, STATE, ZIP CODE, COUNTRY Eumseong, Chungcheongbuk, 27653 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Drug and Cosmetic 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

Drug products failing to meet established specifications and quality control criteria are not rejected.

Specifically,
Your firm failed to reject the following two batches of (b) (4) (b) (4) after receiving OOS results for assay:

-Batch number (b) (4) which was distributed to the US in (b) (4) and has an expiration date of 11/2024. Your assay results reported on the COA for this batch were (b) (4)%, which is above your specification of (b) (4)%-(b) (4)%.

-Batch number (b) (4) which was distributed to the US from (b) (4) to (b) (4) and has an expiration date of 12/2024. Your assay results reported on the COA for this batch were (b) (4)%, which is above your specification of (b) (4)%-(b) (4)%.

OBSERVATION 2

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

Specifically,
A. You do not have an SOP for good documentation practices for your growth promotion testing forms. Correction tape was observed covering original data on multiple pages of the growth promotion testing

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forms. These forms include the handwritten raw data for the growth promotion testing. In addition, there is no secondary review of these forms.

B. Your firm does not have an SOP for validation of any kind. In addition, you have not validated procedures, processes, and methods including, but not limited to, the following:

-Your manufacturing process, including compounding of the solution and packaging of the (b) (4)

-Your cleaning method for manufacturing equipment.

-Your microbiological method for determination of total microbial count in (b) (4) and finished product.

-Your chemical analytical methods, including assay.

These procedures and methods apply to the manufacturing and testing of (b) (4) (b) (4)

C. Your firm lacks a procedure for qualification of manufacturing equipment. In addition, you have not qualified the equipment used in the manufacturing of (b) (4) (b) (4)

D. Your firm lacks a procedure for qualification of raw material suppliers. In addition, you have not qualified any of your raw materials suppliers, including the suppliers used for the (b) (4) (b) (4) API used in (b) (4)

OBSERVATION 3

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Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,
The following discrepancies were identified during a review of your Chrozen HPLC and YL-Clarity version 8.1.0.77 chromatography software:

-The computer used to operate the HPLC lacks security controls to prevent modification and deletion of files. For example, there were 11,567 files in the recycle bin on this computer, which included, but were not limited to, CAL chromatography, MET chromatography, PRM chromatography, and SEQ chromatography file types.

-The chromatography raw data is saved locally on the computer, which is not backed up.

-The computer used for the HPLC does not require user login for the Windows operating system or the YL-Clarity chromatography software.

-The YL-Clarity chromatography software did not have audit trails. In addition, the sequence history was only available for the previous day.

The HPLC was previously used for assay testing of the bulk drug solution used for (b) (4) (b) (4) In addition, you began using the HPLC for finished product assay testing in January 2023.

OBSERVATION 4
GMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically,

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Your employees do not receive annual cGMP training. In addition, your employees in Quality, QC, and Production were not familiar with numerous cGMP requirements including, but not limited to, areas related to validation, qualification, ALCOA, data integrity, and good documentation practices.

OBSERVATION 5

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,
Your stability study SOP, number FC-C-106, does not require at least one batch of (b) (4) (b) (4) to be placed on a stability study each year. In addition, you have never performed a stability study on the (b) (4) at 25°C and 60% relative humidity conditions to demonstrate the product retains its quality attributes throughout the (b) (4) labeled expiry.

OBSERVATION 6

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

Specifically,
Your firm does not perform identity testing on batches of (b) (4) raw material used in (b) (4) (b) (4) In addition, you do not perform specific identity testing for (b) (4) and (b) (4) in (b) (4)

OBSERVATION 7

The (b) (4) system contains defects that could contribute to the contamination of drug products.

Specifically,
Your (b) (4) system consists of a (b) (4) distribution line. Your Production Manager stated the

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distribution line is sanitized with (b) (4) solution (containing (b) (4) (b) (4) prior to the manufacturing of each batch, but (b) (4) of the (b) (4) are flushed. The (b) (4) distribution line is not sanitized when there are no (b) (4) being manufactured and the last time it was sanitized was 08 March 2023. (b) (4) is used as an ingredient in (b) (4)

OBSERVATION 8

The suitability of all testing methods is not verified under actual conditions of use.

Specifically,
Your firm does not perform system suitability checks on your HPLC instrument when conducting assay testing on bulk drug solutions or finished products.

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