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	10/30/2023-11/6/2023*
	FEI NUMBER 3008470621

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Atsuhiko Kimura, Kyoto Plant Manager

FIRM NAME	STREET ADDRESS
Daizo Corporation	704 Yodomizu-Cho, Fushimi; Yodomizu-Cho; Fushimi; Yodomizu-Cho; Fushimi; Yodomizu-Cho; Fushimi
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kyoto, Kyoto, 613-0916 Japan	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 records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically, during my review of your gas chromatography (GC) system, repeated sample analysis was observed on at least four (4) occasions in 2023, including but not limited to testing of two out of the (b) (4) lots of (b) (4) drug product manufactured for the US market. Repeated analysis included:

-Initial GC lot (b) (4) sample analysis conducted on 20 JAN 2023
-Repeated GC lot (b) (4) sample analysis conducted on 21 JAN 2023
-Additional repeated GC lot (b) (4) sample analysis conducted on 23 JAN 2023

-Initial GC lot (b) (4) sample analysis conducted on 18 OCT 2023
-Repeated GC lot (b) (4) sample analysis conducted on 19 OCT 2023

The reason for repeated analysis was not documented, and only the repeated sample analysis results were reported in finished OTC drug product records.

OBSERVATION 2

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.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Seneca D Toms, National Expert X Seneca D Toms National Expert Signed By: 2000592667 Date Signed: 11-06-2023 01:00:24	11/6/2023

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Specifically, there are no written procedures to describe the review of audit trails associated with your gas chromatography software used to analyze products manufactured, including (b) (4) for the US market, to ensure this data has not been changed or deleted. According to interviews with the Quality Control personnel, audit trails are not reviewed.

OBSERVATION 3

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

Specifically, the firm lacks data to support the established cleaning validation specification limits on active pharmaceutical ingredient (API) residue remaining after cleaning of non-dedicated/multi product equipment line (b) (4). The (b) (4) line is used for production of over the counter (OTC) drug products, including (b) (4) and (b) (4) products, which are distributed in the United States and other countries. Additionally, laboratory analysis of cleaning validation swab samples for at least two products manufactured on the line (b) (4) for the non-US market were analyzed by the firm's customer. The customer's laboratories have not been evaluated by the firm to conduct laboratory operations.

***DATES OF INSPECTION**

10/30/2023(Mon), 10/31/2023(Tue), 11/01/2023(Wed), 11/06/2023(Mon)

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