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	3/27/2023-3/29/2023
	FEI NUMBER 3004579906

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kazunori Yoshida, Executive Managing Director

FIRM NAME	STREET ADDRESS
Japan Food Research Laboratories	7 Chome 4-41, Saitoasagi
CITY, STATE, ZIP CODE, COUNTRY Ibaraki, Osaka, 567-0085 Japan	TYPE ESTABLISHMENT INSPECTED Contract Laboratory

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:

Quality

OBSERVATION 1

Employees are not given training in the particular operations they perform as part of their function.

Specifically,

Your training program is deficient. After my discussions with Ms. Kawanishi and Mr. Sato regarding several quality-related procedures including training, complaints, Quality Unit responsibilities, equipment qualifications, OOS, change controls, so forth, they appeared to be not as informed or properly trained as to the procedural content. No responses could readily be provided without constant review of the procedures. I also noted that Mr. Sato had been trained on approximately 21 SOPs on 3//13/23.

OBSERVATION 2

The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically,

When I was reviewing the Out-Of-Specification report for (b) (4) I noted that the QA had not initiated any investigations and only had notified the customer of the incident on 8/15/22. In addition, during my discussions with the QA manager, she stated that the procedures are issued by the

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QC Head and not the QA.

OBSERVATION 3

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

Specifically,

Your firm failed to provide the procedure for water sampling, testing, and sanitization.

Laboratory

OBSERVATION 4

Determinations of conformance to appropriate written specifications for acceptance are deficient in that they are not made for each lot within each shipment of components used in the manufacture, processing, packing or holding of drug products.

Specifically,

Your firm's procedure for retesting of Out-Of-Specification (OOS) results is deficient. The assay test result for (b) (4) tested on 8/12/22 failed the specification. Your firm continued the retesting of the sample up until fourth time before it would pass the specification. Your OOS procedure is also deficient in that it states that the number of retests should be up to (b) (4) retests without any final determination point. In addition, the quality agreement has not outlined the steps in the event of any OOS results and only mentions abnormality.

OBSERVATION 5

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

Specifically,

Your firm failed to provide or explain a procedure on the steps which may be required to validate or verify analytical procedures provided or referred by its clients.

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