DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160 orabioinspectionalcorrespondence@fda.hhs.gov	5/8/2023-5/12/2023
	FEI NUMBER 3014982186

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Eiji Sanada, President

FIRM NAME	STREET ADDRESS
JMS Healthcare PHL Inc.	Lot 2-B-1, Phase 1b, 1st Philippine Ind Park Spec Econ Zone
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tanauan City, Batangas, 4232 Philippines	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Acceptance activities were not documented.

Specifically,

Your standard operating procedure #P-32J002 entitled "Bacterial Endotoxin Test - (b) (4) (b) (4) " section (b) (4) states: " (b) (4) (b) (4) Test the test sample (b) (4) (b) (4) "; and section (b) (4) says: " (b) (4) ". These steps are not documented for any of your product endotoxin testing.

OBSERVATION 2

Procedures for acceptance of incoming product have not been adequately established.

Specifically,

Your standard operating procedure P-30T001 entitled "Application of International Standard ISO 2859-1" outlines the sampling plan for incoming raw materials depending on the lot or batch size and the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brandon L Mariner, FDA Center Employee Irina Gaberman, Investigator	X Brandon L Mariner FDA Center Employee Signed By: Brandon L. Mariner -S Date Signed: 05-12-2023 09:39:33	5/12/2023

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Eiji Sanada, President	
FIRM NAME JMS Healthcare PHL Inc.	STREET ADDRESS Lot 2-B-1, Phase 1b, 1st Philippine Ind Park Spec Econ Zone
CITY, STATE, ZIP CODE, COUNTRY Tanauan City, Batangas, 4232 Philippines	TYPE ESTABLISHMENT INSPECTED Manufacturer

sample size. Review of 11 released lots for (b) (4) from January 2021 to May 2023 found that this operating procedure was not followed for the following incoming raw materials:

(b) (4)	Certificate of Compliance	Part Lot Number/Part Code	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

X Irina Gaberman
Investigator
Signed By: 1300222798
Date Signed: 05-12-2023 09:40:08

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	Brandon L Mariner, FDA Center Employee Irina Gaberman, Investigator	X Brandon L Mariner FDA Center Employee Signed By: Brandon L. Mariner -S Date Signed: 05-12-2023 09:39:33	5/12/2023

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FIRM NAME	STREET ADDRESS
JMS Healthcare PHL Inc.	Lot 2-B-1, Phase 1b, 1st Philippine Ind Park Spec Econ Zone
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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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	Brandon L Mariner, FDA Center Employee Irina Gaberman, Investigator X Brandon L Mariner FDA Center Employee Signed By: Brandon L. Mariner -S Date Signed: 05-12-2023 09:39:33	5/12/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."