DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	8/26/2024-9/6/2024* FEI NUMBER 3024611767

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alexander Oshmyansky, Founder/CEO

FIRM NAME	STREET ADDRESS
Mark Cuban Cost Plus Manufacturing and Compounding LLC	3015 Taylor St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75226-1911	Outsourcing Facility

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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

A. Your firm's sterile filling technicians was observed entering and leaving different ISO 7 classified areas (storage closet, hallway, Sampling/Weighing/Dispensing Room, Formulation, and Filling Rooms which contain the ISO 5 (b) (4) Filling along with (b) (4) performing tasks without adequately disinfecting their sterile gloves adequate frequency to prevent potential contamination as written in your firm's procedure, Aseptic Sterile Drug Processing (Aseptic Technique), DAL-SOP-0227, Rev. 1.0, section Glove Management, sub-sections 8.14 - 8.19.

B. Your firm sterile filling technician was observed utilizing poor technique putting on sterile gloves (b) (4) within ISO 5 (b) (4) (b) (4) prior to the preparation of the (b) (4) environmental monitoring strip into the holder during the production of Epinephrine Injection, USP 5mg/5mL (1mg/1mL), Lot # (b) (4), Actual Qty. (b) (4) vials.

C. Your firm's procedure, DAL-SOP-0237, Cleaning and Disinfection of Cleanroom Areas, failed to ensure sporicidal agent, (b) (4), which require (b) (4) contact time is achieved during the cleaning and deactivation method of production equipment used for weighing of drug components within ISO 7 Formulation Room (RM 033).

D. Your firm sterile drug product technician failed to adequately disinfect sterile (b) (4) spray bottle prior to transfer from ISO 7 Filling Room into ISO 5 (b) (4) for use in setup of (b) (4) stripe into the (b) (4) unit for air sampling inside the (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator Rodney L Tinzie, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 09-06-2024 16:02:20	9/6/2024

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Weighing/ Dispensing Room, Formulation, and Filling Room) were impacted on the 8/26/2024 date between 7:58 am - 8:11 am. The differential pressure was below the minimum of (b) (4) for greater than (b) (4) . Your firm management reported an action limit specification of (b) (4) sustained below the documented specification. Your firm was unaware of this impact prior to this inspection.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm's environmental monitoring program fail to include viable air and surface monitoring sampling in areas of operations most prone to contamination within the ISO 7 Filling Room (RM 0034) that contain the ISO 5 (b) (4) . For example, firm fail to monitor ISO 5 (b) (4) handles, table surface used to hold components for (b) (4) System, and (b) stainless-steel racks used to hold logbooks and (b) (4) components.

OBSERVATION 6

Labeling

1. The container of your outsourcing facility's miglustat suspension drug product did not include information required by section 503B(a)(10)(B). Specifically, your container did not include the following information:

    a. Information to facilitate adverse event reporting: ---www.fda.gov/medwatch and 1800FDA1088 <http://www.fda.gov/medwatch%20and%201800FDA1088>;

    b. Directions for use, including, as appropriate, dosage and administration.

2. The label of your outsourcing facility's miglustat suspension drug product does not include

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information required by section 503B(a)(10)(A). Specifically, the following information is not found on your miglustat suspension bottle label:

a. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Specifically, the Miglustat 100 mg/mL suspension bottle label is missing the "quantity or proportion" of the following ingredients: glyceryl distearate, polyglyceryl-3 oleate, medium-chain triglycerides.

OBSERVATION 7

PRODUCT REPORTING

1. Your outsourcing facility did not submit a report to FDA at the time of initial registration on November 2, 2022, as required for an outsourcing facility that registers with FDA under section 503B.

***DATES OF INSPECTION**

8/26/2024(Mon), 8/27/2024(Tue), 8/28/2024(Wed), 8/29/2024(Thu), 8/30/2024(Fri), 9/03/2024(Tue), 9/04/2024(Wed), 9/05/2024(Thu), 9/06/2024(Fri)

X Rodney L Tinzie
Investigator
Signed By: Rodney Tinzie Jr -S
Date Signed: 09-06-2024 16:02:53

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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."