

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 3/23/2023-3/30/2023*
	FEI NUMBER 3013611763

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sei Dobashi , Factory Manager

FIRM NAME TERUMO YAMAGUCHI CORPORATION	STREET ADDRESS 3-22, Sayama
CITY, STATE, ZIP CODE, COUNTRY Yamaguchi, Yamaguchi, 754-0894 Japan	TYPE ESTABLISHMENT INSPECTED Sterile 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 WE OBSERVED:
OBSERVATION 1
 Representative samples are not taken of each shipment of each lot of components for testing or examination.

 Specifically,

 Representative samples of each batch of (b) (4) component of the (b) (4) used to deliver (b) (4) Injection Solution, are not tested for adequacy to ensure conformance to specifications and functionality with the (b) (4)

OBSERVATION 2
 Backup data is not assured as complete and secure from alteration, erasure or loss through keeping hard copy or alternate systems.

 Specifically,

 Analytical equipment present in the physio-chemistry laboratory is not connected to an un-interruptible power supply, to ensure proper functionality of instrumentation that is susceptible to power loss, power surge and brown out issues. Power interruptions during data acquisition can result in corruption of data.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Marcellinus D Dordunoo, Investigator Melanie W Pishnery, Investigator	Melanie W Pishnery Investigator Signed By: Melanie W. Pishnery - B Date Signed 03-30-2023 00:02: 8 X	DATE ISSUED 3/30/2023

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3/23/2023(Thu), 3/24/2023(Fri), 3/27/2023(Mon), 3/28/2023(Tue), 3/29/2023(Wed), 3/30/2023(Thu)

X
 Marcellinus D Dordunoo
 Investigator
 Signed By: Marcellinus Dordunoo -S
 Date Signed: 03-30-2023 00:03:29

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Marcellinus D Dordunoo, Investigator Melanie W Pishnery, Investigator	DATE ISSUED 3/30/2023 Melanie W Pishnery Investigator Signed By: Melanie W. Pishnery - S Date Signed: 03-30-2023 00:02: 8 X
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