DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CDER/OPQ/OPMA/Division of Biotechnology Manufacturing 10903 New Hampshire Avenue, Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	02/28/2022-03/03/2022 FEI NUMBER 1419377

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ms Heidi Brasile, Senior Director of Quality	
FIRM NAME Woodstock Sterile Solutions, Inc.	STREET ADDRESS 2210 Lake Shore Drive
CITY, STATE, ZIP CODE, COUNTRY Woodstock, IL 60098	TYPE ESTABLISHMENT INSPECTED Drug Product 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

Your firm failed to adequately investigate recurring environmental monitoring excursions. Specifically,

From June to November 2021, your environmental monitoring program repeatedly recovered various mold species from Suite (b) (4) ; Room (b) (4) , Dispensary Suite; and other controlled areas of your (b) (4) manufacturing facility. For example, Laboratory Investigation Records (LIR) #387916, #402868, #405576, #411272, #434285, #435823, #435825, #442765, #447299, #478713, # 430562, #434284, and #447285 were initiated for mold recoveries that exceeded alert and action limits. These investigations failed to determine the root causes and to implement appropriate and effective CAPAs for the remediation of recurring mold recovery issues in your facility.

OBSERVATION 2

No contemporaneous verification of the bioburden test results was performed. Specifically,

On March 1, 2022, in the QC Microbiology Laboratory, I observed a Microbiology Analyst performing microbiology plate reading for bioburden tests in accordance with SOP STW-MIC-0002 Version 30.0. effective 03/05/2021. I observed the Analyst entered the results on the Bioburden Test Report, dated, and signed off. During my observation, one of the plates had a black speck on the membrane surface. The Analyst was going to enter the result as (b) (4) cfu" when I state that there appears to be something on the plate. The Analyst then entered the result as [redacted] cfu as instructed by the Microbiology lab Manager.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Wendy Guat Hoon Tan -S Digitally signed by Wendy Guat Hoon Tan -S Date: 2022.03.03 09:30:46 -05'00'	Wendy Tan, PhD, Microbiologist	3/03/2022

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According to the Analyst and the Microbiology Lab Manager, (b) (4) analyst verification of the bioburden plate reading is not required for bioburden test results reporting. Contemporaneous verification of the bioburden plate reading should be implemented to ensure the integrity of microbiological data that are generated (b) (4) for the samples collected from critical manufacturing processes and areas.

DATES OF INSPECTION: *2/28/2022 (Mon); 3/1/2022 (Tues); 3/22022 (Wed); 3/32022 (Thurs).*

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Wendy Guat Hoon Tan -S Digitally signed by Wendy Guat Hoon Tan -S Date: 2022.03.03 09:31:14 -05'00'	Wendy Tan, PhD, Microbiologist	3/03/2022

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."