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	8/17/2022-8/23/2022* FEI NUMBER 3001236277

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joaquin Villeta-Trigo, Site General Manager

FIRM NAME	STREET ADDRESS
Sterigenics US, LLC	3125 Wichita Ct
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Worth, TX 76140-1755	Contract Sterilizer

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:

LABORATORY SYSTEM

OBSERVATION 1
Deviations from written test procedures are not recorded and justified.

Specifically,

Your firm's SOP entitled, "(b) (4) Test using (b) (4)" Document No. G-WI-RAD-QA-335, Revision 3.0, Effective November 30, 2020, states that the "(b) (4) test" must be performed on the (b) (4) to ensure the instruments (b) (4) accuracy. Initial failures attributed to sample preparation errors may be repeated but a repeated failure requires a written "Calibration Investigation Report". There were several initial and repeated (b) (4) test failures that were not investigated and/or documented. Instead, the analyst repeats the (b) (4) test until it passes. There is no written explanation/justification for this current practice.

Furthermore, your firm relies on the data from the (b) (4) to release batches of drug products that have undergone (b) (4) sterilization and to provide your customers a Certificate of Processing stating that the drug products have achieved adequate exposure during the sterilization process.

QUALITY SYSTEM

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator Timothy H Vo, Investigator Brittny C Cargo, Investigator	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 09-23-2022 13:48:49	8/23/2022

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Joaquin Villeta-Trigo, Site General Manager	
FIRM NAME Sterigenics US, LLC	STREET ADDRESS 3125 Wichita Ct
CITY, STATE, ZIP CODE, COUNTRY Fort Worth, TX 76140-1755	TYPE ESTABLISHMENT INSPECTED Contract Sterilizer

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

a) Your firm's SOP entitled, "Deficiency Handling", Document No. G-WI-QA-002, Revision 14, Effective March 31, 2022 states that the Quality Control Unit is responsible for the timely completion of investigations however, your firm's Quality Control Unit (QCU) repeatedly failed to complete investigations of deficiencies (deviations & non-conformances) within the (b) (4) time frame with/without customer notification as written in your SOP.

b) Similarly, your firm's SOP entitled, "Corrective and Preventative Action (CAPA), Document No. G-WI-QA-005, Revision 15, Effective February 28, 2022 states that the QCU is responsible for closing CAPAs within a (b) (4) of initiation, However, your firm's QCU failed to close all corrective/preventative actions within the (b) (4) time frame as written in your SOP.

OBSERVATION 3

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically,

Your firm's SOP entitled, "Customer Complaints", Document No. G-WI-CUS-001, Revision No. 16, Effective December 31, 2021 states that the Preliminary Investigation and Risk Assessment is to be completed as soon as possible but within (b) (4) of receipt of customer complaint. In addition, it states that the customer follow up is to be conducted a (b) (4) after the preliminary investigation/risk assessment is completed. However, at time of inspection, there were at least seventeen (17) open complaints that exceeded the time frame that have not been resolved.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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Fort Worth, TX 76140-1755	Contract Sterilizer

*DATES OF INSPECTION

8/17/2022(Wed), 8/18/2022(Thu), 8/19/2022(Fri), 8/22/2022(Mon), 8/23/2022(Tue)

X Brittny C Cargo
Investigator
Signed By: Brittny C. Cargo -S
Date Signed: 08-23-2022 13:50:37

X Timothy H Vo
Investigator
Signed By: 2003265410
Date Signed: 08-23-2022 13:51:18

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Patty P Kaewussdangkul, Investigator
Timothy H Vo, Investigator
Brittny C Cargo, Investigator

X Patty P Kaewussdangkul
Investigator
Signed By: Patty P. Kaewussdangkul -S
Date Signed: 08-23-2022 13:48:49

DATE ISSUED
8/23/2022

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."