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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 300 River Place, Suite 5900<br>Detroit, MI 48207<br>(313) 393-8100 Fax:(313)393-8139 | 5/28/2025-6/5/2025*<br>FEI NUMBER<br>1818977 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Richard J. Zuehlk, Vice President, Biologics & Sterile Quality Assurance & Compliance

| FIRM NAME | STREET ADDRESS |
|---|---|
| ENDO USA, Inc. | 870 Parkdale Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Rochester, MI 48307-1740 | Biological 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

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

Specifically, the following actions/behaviors do not conform to the instructions in your Aseptic Processing procedure (VV-SOP-00953).

- During the review of video recording of filling operation of Aplisol (Stabilized Solution) (b) (4) in Suite (b) (4) dated 30th April 2025, we observed an operator repeatedly talking and moving his/her hands in a fast and non-deliberate motion in a Grade (b) (4) manufacturing area. The employee observed was identified as a Trainer.

- During the review of video recording of filling operation of (b) (4) (b) (4) in Suite (b) (4), dated 13th January 2025, we observed operators talking and moving hands in a fast and non-deliberate motion in a Grade (b) (4) manufacturing area.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Lewis K Antwi, Investigator<br>Richard L Bartlett, Investigator | X Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 06-05-2025 11:33:02 | 6/5/2025 |

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## *DATES OF INSPECTION

5/28/2025(Wed), 5/29/2025(Thu), 5/30/2025(Fri), 6/02/2025(Mon), 6/03/2025(Tue), 6/04/2025(Wed), 6/05/2025(Thu)

X Richard L Bartlett
Investigator
Signed By: Richard L. Bartlett -S
Date Signed: 06-05-2025 11:33:44

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Lewis K Antwi, Investigator
Richard L Bartlett, Investigator

X Lewis K Antwi
Investigator
Signed By: 2001796124
Date Signed: 06-05-2025 11:33:02

DATE ISSUED
6/5/2025

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."