DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	11/10/2025-11/21/2025* FEI NUMBER 3004034796

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stuart P. Simpson, President, Co-Owner

FIRM NAME	STREET ADDRESS
Delta Pharma, Inc.	114 W Mulberry St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ripley, MS 38663-1709	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 I OBSERVED:

OBSERVATION 1

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, the semaglutide finished product primary labels for batches 05-0325-001, 05-0425-001, 05-0525-001, 05-0525-002, and 05-0525-003, do not include the following information: Address of your firm, and the statements "NOT FOR RESALE" and "OFFICE USE ONLY".

Material System

OBSERVATION 2

Approved components are not retested or reexamined as appropriate for identity, strength, quality and purity after storage for long periods with subsequent approval or rejection by the quality control unit.

Specifically, the raw material, Sterile water for Injection, USP, lot (b) (4), expiration date 31March2025, was used in the production of the finished product, Semaglutide 2.5mg/mL, product batch 02-0225-001, expiration date 02 April 2025. The lot produced (b) (4) vials which were distributed for commercial use.

*DATES OF INSPECTION

11/10/2025(Mon), 11/12/2025(Wed), 11/13/2025(Thu), 11/14/2025(Fri), 11/17/2025(Mon), 11/21/2025(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jared P Stevens, Investigator	X Jared P Stevens Investigator Signed By: JARED P. STEVENS - S Date Signed: 11-21-2025 09:31:32	11/21/2025

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EMPLOYEE(S) SIGNATURE

Jared P Stevens, Investigator

X Jared P Stevens
Inves igator
Signed By: JARED P. STEVENS -
S
Date Signed: 11-21-2025
09:31:32

DATE ISSUED

11/21/2025

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."