DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 ORAPHARM2_RESPONSES@fda.hhs.gov	5/22/2023-6/2/2023* FEI NUMBER 3004034796

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

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 WE OBSERVED:
OBSERVATION 1
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm failed to perform environmental monitoring (EM) sampling (viable and non-viable) in the ISO 7 room during the media fill on 5/26/2023. Because of the absence of EM sampling, the firm lacks the assurance of control of the ISO 7 room. Further, your firm's media fill is not representative of your established drug production process where EM samples of the ISO 7 room are collected no less than (NLT) one time during filling.

***DATES OF INSPECTION**
5/22/2023(Mon), 5/23/2023(Tue), 5/24/2023(Wed), 5/25/2023(Thu), 5/26/2023(Fri), 5/30/2023(Tue), 5/31/2023(Wed), 6/01/2023(Thu), 6/02/2023(Fri)

X Lareese K Thomas
Field Administrative Personnel
Signed By: Lareese K. Thomas -S
Date Signed: 06-02-2023 10:34:37

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sonya M Edmonds, Investigator Lareese K Thomas, Field Administrative Personnel X Sonya M Edmonds Investigator Signed By: Sonya M. Edmonds -S Date Signed: 06-02-2023 10:33:50	6/2/2023

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."