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 ORAPHARM2_RESPONSES@fda.hhs.gov	4/9/2024-4/12/2024 FEI NUMBER 3004034796

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Stuart P. Simpson, President	
FIRM NAME Delta Pharma, Inc.	STREET ADDRESS 114 W Mulberry St
CITY, STATE, ZIP CODE, COUNTRY Ripley, MS 38663-1709	TYPE ESTABLISHMENT INSPECTED 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

Written procedures are not established that describe the in-process controls, tests and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically, your firm has no written procedures for performing a supplemental visual inspection of drug products where the drug products and/or the container closure system permits limited inspection of the contents. Your firm fills Brompheniramine Maleate 10 mg/mL sterile injectable into (b) (4) vials. Lot #(b) (4) was compounded and (b) (4) on September 19, 2023 and filled on September 20, 2023. The lot was released for distribution on November 14, 2023.

OBSERVATION 2

Written procedures are not followed for the sampling and testing of components.

Specifically, on May 31, 2022 your firm received (b) (4) of Brompheniramine Maleate, USP API and assigned it Raw Material Receiving #(b) (4) On February 7, 2022, your received in (b) (4) of Brompheniramine Maleate, USP API and assigned it Raw Material Receiving #(b) (4). While they were the same vendor lot number, they were received in different shipments almost four (4) months apart. Your firm used the test results for the product received under Raw Material Receiving #(b) (4), including identity, assay, loss on drying, and microbial limits testing to release the product received under Raw Material Receiving #(b) (4). The Brompheniramine Maleate, USP API received under Raw Material Receiving #(b) (4) was then used to manufacture lot #(b) (4) of Brompheniramine

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M Annes, CSO X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 04-12-2024 11:59:01	4/12/2024

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Maleate 10 mg/mL sterile injectable that was compounded and (b) (4) on September 19, 2023 and filled on September 20, 2023. The lot was released for distribution on November 14, 2023.

OBSERVATION 3

Representative samples are not taken of each shipment of each lot of components for testing or examination.

Specifically, GMP-SOP-0024 Receipt, Evaluation, and Dispositioning of Materials, revision 3 effective July 20, 2021, does not define a statistically sound sampling plan for raw materials (APIs and excipients) when more than one container is received in for a lot/batch. For example, on February 7, 2022, your received in (b) (4) of Brompheniramine Maleate, USP API and assigned it Raw Material Receiving #(b) (4). Your firm sent (b) (4) containers to your contract testing laboratory for testing.

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	Margaret M Annes, CSO	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 04-12-2024 11:59:01	4/12/2024

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."