DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	3/6/2023-3/24/2023* FEI NUMBER 3018035065

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kuppusamy G. Arumugam, President/Owner

FIRM NAME	STREET ADDRESS
Delsam Pharma LLC	55 E Gun Hill Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bronx, NY 10467-2103	Own-Label Distributor

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

There is no quality control unit.

Specifically, your firm imported and distributed your own-label drug products, Delsam Pharma's Artificial Tears (NDC 72570-121-15) and Delsam Pharma's Artificial Eye Ointment (NDC 72570-122-35). However, your firm failed to carry out the following quality control duties:

(A) Your firm has not established with its contract manufacturing organization (CMO) an agreement which delineates the CGMP-related roles and activities of each party in ensuring the safety, efficacy, and quality of its own-label drug products.

(B) Your firm has not qualified its CMO to ensure its contracted supplier will supply drug products which meet quality standards or ensuring its contracted warehouse/fulfillment center will hold drug products under conditions which meet CGMP requirements.

(C) Your firm has not ensured the certificate of analyses provided by its CMO are reliable and accurate to ensure that the drug products are suitable to be released for distribution.

(D) Your firm does not have written procedures regarding critical quality control unit functions including, but not limited to, procedures for handling deviations, out-of- specification (OOS) or out-of-trend (OOT) results from its supplier and procedures for reviewing and assessing stability data, and development and approval of release specifications for its own-label products.

(E) Your firm did not track or investigate product complaints and product returns.

OBSERVATION 2

Drug products are not stored under appropriate conditions of temperature and humidity so that their identity, strength, quality, and purity are not affected.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mindy M Chou, Investigator X Mindy M Chou Investigator Signed By 2000648922 Date Signed 03-24-2023 12 02 57	3/24/2023

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Specifically, as per the product labeling, the storage condition for Delsam Pharma's Artificial Tears (NDC 72570-121-15) and Delsam Pharma's Artificial Eye Ointment (NDC 72570-122-35) is 15-30 °C and 20-25 °C, respectively. According to the President of Delsam Pharma's LLC, (b) (4) units of Delsam Pharma's Artificial Tears (Lot # PCMH001, # PCMH002, # PCMH003, # PCMH004, # PCMH005, # PCMH006, # PCMH007, and # PCMH008) and (b) (4) units of Delsam Pharma's Artificial Eye Ointment (Lot # H29) were stored in a public storage facility on or about July 12, 2021 to August 31, 2021. These lots of products were stored in an area without temperature monitoring. There is no assurance that these lots of sterile drug products were stored within labeled storage conditions during this 1.5 month period and were subsequently released for distribution within the U.S. Additionally, your firm does not have a procedure for the storage and warehousing of drug products.

OBSERVATION 3

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

Specifically, your firm does not have written procedures describing the handling of all written and oral complaints regarding its own-label drug products, including determination of whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration. Below are some of the examples of complaints which your firm has received:

Awareness Date	Complaint Received From	Product	Nature of Complaint
On or about 02/06/2023	Forwarded from FDA (MSB # 2023-04406)	Artificial Eye Ointment	Tubes were received without safety seals and the tubes leaked when squeezed
On or about 02/13/2023	Forwarded from FDA (MSB # 2023-05159)	Artificial Tears (Lot # PCMH006)	Developed conjunctivitis in both eyes after use
02/25/2023	End user via email	Artificial Eye Ointment	Developed severe eye infection after use
02/25/2023	End user via email	Artificial Eye Ointment	Experienced adverse effects after use
02/28/2023	End user via email	Artificial Eye Ointment	Developed eye infection after use
03/02/2023	End user via email	Artificial Eye Ointment	Developed bad eye infection after use

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OBSERVATION 4

A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary, has not been established.

Specifically, your firm and your third-party logistics (3PL) did not maintain records of the drug product lots which were shipped to its customers for identifying and tracing of the distributed lots. Your firm also does not have a recall procedure in place.

OBSERVATION 5

Written procedures are not established for evaluations done at least annually and including provisions for a review of complaints, recalls and returned or salvaged drug products.

Specifically, your firm has not conducted any annual product review for its drug products, Delsam Pharma's Artificial Tears (NDC 72570-121-15) and Delsam Pharma's Artificial Eye Ointment (NDC 72570-122-35) nor has your firm established an agreement with its contract manufacturing organization (CMO) to conduct the annual product review on behalf of Delsam Pharma LLC.

***DATES OF INSPECTION**

3/06/2023(Mon), 3/10/2023(Fri), 3/22/2023(Wed), 3/24/2023(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mindy M Chou, Investigator X Mindy M Chou Investigator Signed By: 2000648922 Date Signed: 03-24-2023 12:02:57	3/24/2023

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."