DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787)729-8500 Fax:(787)729-6809	3/16/2026-3/20/2026 FEI NUMBER 2650091

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ruben De Quesada, General Manager

FIRM NAME	STREET ADDRESS
Omega & Delta Co., Inc.	Carr. 887 Km 0 Hm 8 Julio N. Matos Ind. Park Bldg#10
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Carolina, PR 00985	OTC- 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 I OBSERVED:

OBSERVATION 1

Written procedures are not followed for evaluations done at least annually and including provisions for a review of investigations conducted for each drug product.

Specifically,

Your firm failed to follow your Standard Operating Procedure (SOP) J0102 Rev. 03, Annual Product Review for 2025, in a timely manner. Section 7.7 of the SOP states, "The Annual Product Report covers the period from (b) (4) . It must be carried out no later than (b) (4) and will analyze the data of the (b) (4) ." The Annual Product Review for the 2025 (b) (4) was not completed by the following (b) (4) deadline as required by the procedure.

OBSERVATION 2

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

Your firm does not have written procedures for rework/reprocessing. During the review of your 2024 and 2025 (pending completion) Annual Product Reviews (APRs), I observed that your firm performed

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Tomika L Crafter, Investigator	X Tomika L Crafter Investigator Signed By: TOMIKA L. CRAFTER -5 Date Signed: 03-20-2026 11:48:13	3/20/2026

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CITY, STATE, ZIP CODE, COUNTRY Carolina, PR 00985	TYPE ESTABLISHMENT INSPECTED OTC- Drug Manufacturer

rework/reprocessing on lots: (b) (4)

and (b) (4) . There is no standard operating procedure for the reprocessing of Over-the-Counter (OTC) products.

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tomika L Crafter, Investigator X Tomika L Crafter Investigator Signed By: TOMIKA L. CRAFTER -S Date Signed: 03-20-2026 11:48:13	3/20/2026

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."