DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	11/15/2022-11/30/2022* FEI NUMBER 3012258924

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sundeep Thakrar, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
CareFirst Specialty Pharmacy LLC	400 Fellowship Road, Suite 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mount Laurel, NJ 08054	Producer of non-sterile drug products

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

Non-microbial contamination was observed in your production area.

Specifically, unidentified residue buildup was observed during the walkthrough conducted on 11/15/2022 in both corners of the back wall of Bench 101 which was used to produce drug products.

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*DATES OF INSPECTION

11/15/2022(Tue), 11/16/2022(Wed), 11/17/2022(Thu), 11/21/2022(Mon), 11/23/2022(Wed), 11/30/2022(Wed)

X Kristina L Conroy
Investigator
Signed By: Kristina L. Conroy -S
Date Signed: 11-30-2022 11:25:45

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christina K Theodorou, Investigator Kristina L Conroy, Investigator X Christina K Theodorou Investigator Signed By: Christina K. Theodorou -S Date Signed: 11-30-2022 11:25:05	11/30/2022

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."