U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
Telephone: (973) 331-4900
FAX: (973) 331-4969
www.fda.gov

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

March 31, 2023

Via Email
Anthony Rubinaccio
Executive Director
PO Box 45013
Newark, NJ 07101
Email: rubinaccioa@dca.njoag.gov

CMS #437031, FEI # 3012258924

State Referral Letter

Dear Mr. Rubinaccio:

The purpose of this letter is to refer to you, the NJ Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor practices observed during an FDA inspection at a pharmacy you licensed, CareFirst Specialty Pharmacy, LLC, located at 400 Fellowship Road, Suite 100, Mount Laurel, NJ 08054

FDA inspected the firm from November 15, 2022, to November 30, 2022. You were informed of the inspection but did not accompany FDA investigators during the inspection.

A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/164956/download. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

CareFirst committed to FDA in its response to the Form FDA 483, received on December 4, 2022, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the records, FDA does not intend to take further action at this time with regard to the findings of this inspection. FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to you for follow up to ensure appropriate corrective action has been taken. We believe you, the State, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce.

Please notify us if you become aware of any adverse events or product quality concerns associated with drug products made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Yvette Johnson, Compliance Officer, by email at Yvette.Johnson@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

Lisa M. Harlan -S

Digitally signed by Lisa M. Harlan -S
Date: 2023.03.31 15:11:02 -04'00'

Lisa Harlan
Program Division Director
U.S. Food and Drug Administration
OPQO Division I

Cc:

Sundeep Thakrar, RPh
Pharmacist-in-Charge
CareFirst Specialty Pharmacy, LLC
400 Fellowship Road, Suite 100
Mount Laurel, NJ 08054
Email: sthakrar@cfspharmacy.com