



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

March 31, 2023

**Via Email**

Anthony Rubinaccio  
Executive Director  
PO Box 45013  
Newark, NJ 07101  
Email: [rubinaccioa@dca.njoag.gov](mailto: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.

**Office of Pharmaceutical Quality Operations, Division of Pharmaceutical Quality Operations I**

New England District Office: One Montvale Avenue, 4th Floor Stoneham, MA 02180-3500 T- (781) 587-7500 F- (781) 587-7556

New York District Office: 158-15 Liberty Ave Jamaica, NY 11433 T-(718) 340-7000 F-(718) 662-5661


Philadelphia District Office: US Customs House Room 900, 200 Chestnut St. Philadelphia, PA 19106 T- (215) 597-4390 F-(215) 597-4660

Baltimore District Office: 6000 Metro Drive, Suite 101 Baltimore, MD 21215 T-410-779-5455 F- 410-779-5407

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](mailto:Yvette.Johnson@fda.hhs.gov). Please use the reference numbers cited in the heading of the document.

Sincerely,

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

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

Cc:

Sundeeep Thakrar, RPh  
Pharmacist-in-Charge  
CareFirst Specialty Pharmacy, LLC  
400 Fellowship Road, Suite 100  
Mount Laurel, NJ 08054  
Email: [sthakrar@cfspharmacy.com](mailto:sthakrar@cfspharmacy.com)