U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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July 20,2023

Via Email

Dina Jazrawi, Executive Secretary
New York State Board of Pharmacy
89 Washington Avenue, 2nd Floor W
Albany, New York 12234-1000
Email: pharmbd@nysed.gov

CMS #494767; FEI # 3015468054

State Referral Letter

Dear Dr. Jazrawi:

The purpose of this letter is to refer to you, the New York State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy you licensed, Maimonides Medical Center – Pharmacy, located at 4802 10th Avenue, Brooklyn, NY 11219-2916.

FDA inspected the firm from February 14, 2023, to March 9, 2023. FDA investigators were accompanied by your state investigators for part of the inspection.

A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/169793/download, with any nonpublic information redacted. 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.

During the inspection, the FDA investigators reviewed a small sample of records for drug products compounded by Maimonides Medical Center – Pharmacy and FDA does not intend to take further actions at this time related to conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Additionally, the FDA investigators observed deviations from appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Maimonides Medical Center – Pharmacy committed to FDA in its response to the Form FDA 483, received March 30, 2023, 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 Harlan
Program Division Director
U.S. Food and Drug Administration
OPQO Division I

Cc:
Kenneth Gibbs, CEO
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