July 7, 2017

Kimberly A. Leonard
Executive Secretary
New York State Education Department
Office of the Professions, Pharmacy
89 Washington Ave, 2nd Floor W
Albany, NY 12234-1000

Dear Ms. Leonard:

The purpose of this letter is to refer to 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 licensed by the New York BOP, MasterPharm, LLC (MasterPharm), located at 115-02 Liberty Avenue, South Richmond Hill, NY 11419-1902 (license number #025424).

FDA inspected the firm from January 17, 2017, to January 30, 2017. An FDA investigator was accompanied by an investigator from the Special Projects Unit of the Office of Professional Discipline of the New York State Education Department on the first day of the inspection. A copy of the Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm542106.pdf, 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 you are a Commissioned Official or 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 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by MasterPharm and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

During the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. For example, our investigator noted that the firm failed to conduct adequate aspetic processing simulations (e.g., media fills).

In its response to the Form FDA 483, dated February 15, 2017, and March 6, 2017, MasterPharm

committed to correct the deviations in the Form FDA 483 and provided supporting documentation. In addition, the deviations identified appear to be readily correctable.

After review of records post-inspection, FDA also noted that some bulk drug substances used in compounding by the firm are not eligible for the exemptions provided by subsection (a) of 503A because the the bulk drug substances are not the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, not components of an FDA-approved human drug, and do not appear on a list of bulk drug substances that my be used for compounding developed by the Secretary (see our final guidance, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf. FDA notified MasterPharm on April 13, 2017, of the violation and the firm committed to FDA in its response dated April 13, 2017, to correct the violation.

FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the New York State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs 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 Frank Verni, Compliance Officer, at (718) 662-5702, or by email at Frank.Verni@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
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Date: 2017.07.07 13:19:02 -04'00'

Diana Amador-Toro
District Director
New Jersey District
Office of Regulatory Affairs
U.S. Food and Drug Administration

cc: Stephen S. Laddy, CEO
MasterPharm, LLC
11502 Liberty Avenue
South Richmond Hill, NY 11419-1902