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

November 7, 2016

Kimberly A. Leonard, Executive Secretary
New York State Board of Pharmacy
89 Washington Avenue, 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 State BOP, Pine Pharmacy and Home Care Products Center, Inc., dba Pine Pharmacy, located at 5110 Main Street, Williamsville, NY 14221 (License # 026390).

FDA inspected the firm from March 30, 2016, to April 18, 2016. The FDA investigator was accompanied by a New York State investigator for the first three days of the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM501730.pdf.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Pine Pharmacy and Home Care Products Center, Inc. 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 dispenses. In the response to the Form FDA 483, dated April 29, 2016, the firm advised FDA that it "engages in the preparation of compounded sterile preparations…" and "[fills] patient-specific orders."

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, an operator's neck was not fully covered allowing their neck skin to be exposed over the ISO 5 laminar flow area while producing products intended to be sterile.

Pine Pharmacy and Home Care Products Center, Inc. committed to FDA in its response to the Form FDA 483, dated April 29, 2016, to correct the deviations in the Form FDA 483. In addition, the deviation identified appears to be readily correctable.

U.S. Food and Drug Administration
New York District
158-15 Liberty Ave
Jamaica, NY 11433
www.fda.gov

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients, consistent with traditional pharmacy practice, 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 human or animal 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, CDR Frank Verni, Compliance Officer, at (718) 662-5702, or by email at Frank.Verni@fda.hhs.gov.

Sincerely,

Matthew R. Palo
Lieutenant Commander, U.S. Public Health Service
District Director (acting)
New York District