U.S. FOOD & DRUG ADMINISTRATION

January 9, 2017

Kimberly A. Leonard
Executive Secretary
New York State Education Department
Office of the Professions
State Board of Pharmacy
89 Washington Avenue
Albany, New York 12234-1000

Dear Ms. Leonard:

The purpose of this letter is to refer to the New York State Board of Pharmacy (NYBOP) 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, Town Total Compounding Center, located at 532 Broadhollow Road, Melville, NY 11747-3672 (Pharmacy license #030816).

FDA inspected the firm from April 4, 2016, to April 20, 2016. NY BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A redacted 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/UCM505816.pdf.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Town Total Compounding Center 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, received May 11, 2016, the firm advised FDA that it "compounds and dispenses sterile and non-sterile human medications pursuant to a patient specific prescription in compliance with section 503A of the Federal Food, Drug, and Cosmetic Act."

During the inspection, the FDA investigator observed deviation from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, smoke studies were not performed under dynamic conditions for the ISO 5 laminar flow hoods.

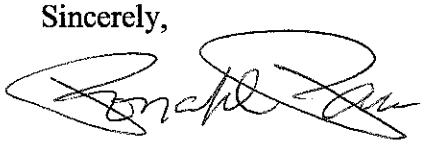
U.S. Food and Drug Administration
New York District
158-15 Liberty Ave
Jamaica, NY 11433
www.fda.gov

Town Total Compounding Center committed to FDA in its response to the Form FDA 483, received May 11, 2016, to correct the deviation in the Form FDA 483. In addition, the deviation identified appears to be readily correctable.

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, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the NYBOP 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 CDR Frank Verni, Compliance Officer, at (718) 662-5702, or by email at Frank.Verni@fda.hhs.gov.

Sincerely,



Ronald M. Pace
District Director
New York District Office