



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
New York District Office
158-15 Liberty Ave.
Jamaica, NY 11433

April 21, 2015

Lawrence H. Mokhiber
Executive Secretary
New York State Board of Pharmacy
89 Washington Ave, 2nd Floor W
Albany, NY, 12234-1000

Dear Mr. Mokhiber:

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, Sina Drug LLC/dba Onco360, aka OncoMed Pharmaceutical Services (Onco360), located at 225 Community Drive, Suite 100, Great Neck, NY 11021 (Licensed Pharmacy # 17 025289 and Licensed Wholesaler # 21 026102).

FDA inspected the firm from August 7, 2014, to August 22, 2014. The New York State BOP was informed of the inspection, and FDA investigators were accompanied by New York State investigators for one day. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM421976.pdf>

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Onco360 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.

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm's program to ensure that each process used is able to produce sterile product without contamination and to evaluate the competency of all personnel who engage in these operations

is inadequate. For example, personnel do not perform media fills under conditions that closely simulate the most challenging or stressful conditions encountered during routine aseptic operations.

2. The firm failed to demonstrate through appropriate studies that their hoods are able to provide adequate protection of the ISO 5 areas in which sterile products are processed. Therefore, their products may be produced in an environment that poses a significant contamination risk. Additionally, unfiltered air is blown into the ISO 7 clean room by a stand-alone air conditioner that could be a reservoir for contaminants.
3. The firm did not perform adequate cleaning and disinfection of the work surfaces, supplies, and equipment within the aseptic processing areas. The investigators observed that sporicidal agents were not used in the hoods to kill microbial spores that could be present in the ISO 5 areas.
4. The firm's non-viable environmental monitoring program for the ISO 5 and 7 areas is inadequate. For example, the firm's environmental monitoring program does not include testing under dynamic conditions (conditions that simulate production activities).

The deviations noted in the Form FDA 483 were readily correctible, and Onco360 committed to FDA in its response, received September 12, 2014, to correct them.¹

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 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 LCDR Frank Verni, Compliance Officer, at 718-662-5702, or by email at frank.verni@fda.hhs.gov.

Sincerely,



Ronald M. Pace
District Director
U.S. Food and Drug Administration
New York District Office

¹ Because you are an FDA commissioned official, you can request an unredacted copy of the Form FDA 483 or the firm's response to the Form FDA 483 received by FDA on September 12, 2014.