



May 8, 2017

Kimberly A. Leonard, Executive Secretary  
New York State Board of Pharmacy  
89 Washington Avenue, 2<sup>nd</sup> 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, Alexander Infusion, LLC, dba Avanti Health Care Services, located at 75 Nassau Terminal Road, New Hyde Park, NY 11040 (license # 17 023601).

FDA inspected the firm from July 20, 2016, to August 1, 2016. The New York State BOP was informed of the inspection but did not accompany the FDA investigator during 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/ORAElectronicReadingRoom/UCM519476.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 Alexander Infusion 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. Examples of deviations observed during our inspection include:

**U.S. Food and Drug Administration**  
New York District  
158-15 Liberty Ave  
Jamaica, NY 11433  
[www.fda.gov](http://www.fda.gov)

1. FDA investigators observed an operator's head, some exposed facial skin, exposed shoulders and arms entering the ISO 5 Laminar Flow Hood (LFH) while producing sterile drug products.
2. There is no established contact time for the sporicidal agent used to disinfect the aseptic processing area to ensure sporicidal activity.
3. Airflow pattern studies were not conducted under dynamic conditions to simulate the most challenging preparations produced by personnel on a regular basis to verify that operators, processing equipment or activities for the-ISO 5 LFHs where drug products are aseptically processed and on the ISO 7 clean rooms do not alter or impede the unidirectional flow of air from the HEPA filters.

Alexander Infusion committed to FDA in its responses to the Form FDA 483, dated August 16, 2016, and September 20, 2016, and in its December 1, 2016 response to FDA's Request for Additional Information dated November 7, 2016, to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctable.

After review of the record, 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 CDR Frank Verni, Compliance Officer, (718) 662-5702, or by email at [Frank.Verni@fda.hhs.gov](mailto:Frank.Verni@fda.hhs.gov).

Sincerely,



Ronald Pace  
District Director  
New York District