DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
New Jersey District Office
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

February 21, 2014

VIA – Certified Mail –
Return Receipt Requested
Anthony Rubinaccio
Executive Director
New Jersey State Board of Pharmacy
PO Box 45013
Newark, NJ 07101

Dear Mr. Rubinaccio:

The purpose of this letter is to refer to the New Jersey 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 of a pharmacy licensed by the New Jersey State BOP, Drugs are Us, Inc. dba Hopewell Pharmacy, located at 1 W Broad Street, Hopewell, New Jersey 08525-1901.

FDA inspected the firm from March 18, 2013 to March 21, 2013. FDA's investigators were not accompanied by New Jersey State BOP inspectors for the inspection. Attached is a redacted copy of the Form FDA 483 that documents our investigators' observations from the inspection.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Hopewell Pharmacy 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 viable environmental monitoring program ensuring microbiological quality of the ISO 5 area is inadequate. Review of the firm's environmental monitoring sample log revealed that the Pharmacist filled out the sampling log as a work order for the technician to collect environmental monitoring samples, and then signed the sampling log on the "Reviewed By" line before the samples were collected. The technician responsible for the environmental monitoring did not collect the viable air samples and as a result the samples were not placed in the incubator. Finally, when samples are collected, the firm is

not able to provide assurance that the media used in the environmental monitoring can support growth.

2. The firm's aseptic processing areas are deficient regarding the system for monitoring environmental conditions. For example, the firm does not monitor the pressure differential between the ISO 6 and ISO 7 areas; ISO 7 and ISO 8 areas; and ISO 8 and the uncontrolled office.

3. The firm does not conduct adequate qualification studies to assess whether proper particle control dynamics have been achieved throughout the ISO 5 area. For example, the firm cannot provide assurance that non-viable particle counts were performed under dynamic conditions.

4. The firm failed to provide sufficient data demonstrating the chemical stability and sterility of injectable drug products throughout their beyond use dates. Although the firm claimed they use formulations from the [redacted] (b) (4) [redacted] and the [redacted] (b) (4) that support their beyond use dates, FDA investigators discovered discrepancies between the professional journals and the firm's practices including; sterilization method, use of preservatives, pH of compounded drugs, and materials used in compounding.

Drugs Are Us, Inc. dba Hopewell Pharmacy committed to FDA in its April 10, 2013, response to the Form FDA 483 to correct some of the deviations.

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. In addition, the deviations identified appear to be readily correctable, and the firm has agreed in writing to correct some of the deviations. Therefore, FDA believes that the corrective actions can be appropriately overseen by the State, and is referring this matter to the New Jersey 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 Erin McCaffery, Compliance Officer, at 973-331-4993, or by email at erin.mccaffery@fda.hhs.gov.

Sincerely,

Diana Amador Toro

Diana Amador Toro
District Director
New Jersey District Office