DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
New England District Office
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June 07, 2016

Michael R. Dupuis, R.Ph., MHA
Executive Director

State of New Hampshire Board of Pharmacy
121 South Fruit Street
Concord, NH 03301-2412

Dear Mr. Dupuis:

The purpose of this letter is to refer to the New Hampshire 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 Hampshire BOP, Anderson Holdings Inc., dba Wingate's Pharmacy & Compounding, located at 129 Main Street, Nashua, NH 03060 (Pharmacy License number #0003).

FDA inspected the firm from February 1, 2016, to February 19, 2016. FDA investigators were accompanied by New Hampshire state investigators for two days. A 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/ucm490611.pdf.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Anderson Holdings, Inc., dba Wingate's Pharmacy & Compounding, 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. For example the firm uses non-sterile cleaning agents for cleaning and disinfecting surfaces in the ISO 5 glove box. Additionally the firm uses non-sterile non-shedding wipes to clean the interior of the ISO 5 glove box. Anderson Holdings Inc., dba Wingate's Pharmacy & Compounding, committed to correct the deviations in its February 29, 2016,

response to the Form FDA 483. A copy of the firm's response to the Form FDA 483 can be found at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM494031.pdf. In addition, the deviations identified appear to be readily correctable.

After review of the record and 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 Hampshire 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 Rory Geyer, Compliance Officer, at 781-587-7521, or by email at Rory.Geyer@fda.hhs.gov.

Sincerely,

Joseph S. Matrisciano Jr -S

Digitally signed by Joseph S. Matrisciano Jr -S
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Joseph Matrisciano Jr
District Director
U.S. Food and Drug Administration
New England District Office