DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New England District Office
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April 29, 2015

Charles J. Fanaras, RPh
Acting Executive Secretary/President
New Hampshire State Board of Pharmacy
121 South Fruit Street
Concord, NH 03301-2412

Dear Mr. Fanaras:

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 State BOP, Northern New England Compounding Pharmacy, LLC, doing business as Eastern States Compounding Pharmacy, located at 338 Union St., Littleton, NH 03561 (In-pharmacy license number 0682).

FDA inspected the firm from September 17, 2014, to September 30, 2014. The New Hampshire State BOP was informed of the inspection, and the FDA investigator was accompanied by New Hampshire State investigators for each day of 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/UCM431095.pdf.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Eastern States Compounding 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 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:

1. The firm did not perform adequate cleaning and disinfection of the work surfaces, supplies, and equipment within the aseptic processing areas. For example, the investigator observed that non-sterile disinfectants were used in the ISO-5 hoods and sporicidal agents were not used in the ISO-5 hoods to kill microbial spores that could be present in the ISO 5 areas.

2. The firm did not adequately establish procedures to define actions when environmental monitoring limits for microbial contamination are exceeded.

Eastern States Compounding Pharmacy committed to FDA in its response to the Form FDA 483, dated October 8, 2014, to correct some of the deviations in the Form FDA 483. In addition, the deviations identified appear 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, 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 Matrisciano Jr.
Acting District Director
U.S. Food and Drug Administration
New England District Office

Original:

Addressee

Copies:

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