U.S. Food and Drug Administration
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FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

April 1, 2020

Geraldine L. Betts
Board Administrator
Maine State Board of Pharmacy
35 State House Station
Augusta, ME 04333

Dear Ms. Betts:

The purpose of this letter is to refer to the Maine State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about practices observed during an FDA inspection at a pharmacy licensed by the Maine BOP, M Drug LLC, dba Northern Light Pharmacy, located at 210 State Street, Bangor, ME 04401 (Pharmacy license #PH50001487).

FDA inspected the firm from July 16, 2019, to July 19, 2019. The FDA investigator was accompanied by a Maine state investigator for two days. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/132017/download, 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 M Drug LLC, dba Northern Light 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 distributes.

Additionally, during the inspection, the FDA investigator observed deviations from appropriate 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. Hazardous drugs were produced without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

   Specifically,

A. There is no designed control of airflow direction or pressure differential between the compounding room and adjacent uncontrolled areas to contain hazardous drug substances.

B. Clean non-dedicated compounding equipment are stored exposed in racks and shelving adjacent to the compounding bench.

C. Non-dedicated utensils are not cleaned by methods and cleaning agents shown to adequately remove drug residues to prevent cross contamination during subsequent use on other drug products.

D. Compounding room work surfaces are not cleaned by methods and cleaning agents shown to remove or de-activate hazardous drug compound residues.

M Drug LLC, dba Northern Light Pharmacy committed to FDA in its responses to the Form FDA 483 received on August 9, 2019, and September 13, 2019, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. 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 Maine 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 Liatte Closs, Compliance Officer, at 973 331-4933, or by email at Liatte.Closs@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
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Diana Amador-Toro
Program Division Director/District Director
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Division I/New Jersey District Office

Cc: Lucas J. Bayne, Pharmacist in Charge
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