U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

September 26, 2017

David Sencabaugh
Executive Director
Massachusetts State Board of Registration in Pharmacy
293 Causeway Street, 5th Floor, Suite 500
Boston, MA 02114

Dear Mr. Sencabaugh:

The purpose of this letter is to refer to the Massachusetts State Board of Registration in Pharmacy (BORIP) 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 Massachusetts BORIP, New England Home Therapies, Inc., located at 337 Turnpike Road, Southborough, MA, 01772-1760 (Retail Drug Store Permit #DS3486).

FDA inspected the firm from January 11, 2016, to January 27, 2016. FDA investigators were accompanied by Massachusetts state investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm490846.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 investigators reviewed a small sample of records for products compounded by New England Home Therapies, Inc. 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. In a response to the Form FDA 483, dated March 11, 2016, the firm advised FDA that it "compounds and dispenses primarily low-risk sterile patient-specific medications pursuant to receipt of a patient-specific prescription form a licensed prescriber."

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. Drug production supplies were not sanitized prior to being placed in the ISO 5 hoods.

2. The firm used non-sterile wipes to clean and disinfect the ISO 5 hoods.

3. The investigators observed stains on the HEPA filters in two of the ISO 5 hoods.

4. The investigators observed chips in two painted window frames in the ISO 7 area. The chips allowed for exposed wood in the ISO 7 area.

5. The firm did not establish an adequate contact time for their sporicidal agent used to disinfect the aseptic processing areas.

New England Home Therapies, Inc. committed to FDA in its written responses, dated March 11, 2016, and May 31, 2017, 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 Massachusetts State BORIP 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 Maya M. Davis, Compliance Officer, at (860) 240-4289 ex. 25, or by email at maya.davis@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300011579, cn=Diana Amador-toro -S
Date: 2017.09.27 14:42:58 -04'00'

Diana Amador-Toro
Division Director/OPQ Division 1
New Jersey District Office

CC: Mr. Stephen P. Berube, General Manager
New England Home Therapies, Inc.
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Southborough, MA 01772