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

September 24, 2018

David Sencabaugh, R.Ph.
Executive Director
Massachusetts Board of Registration in Pharmacy
239 Causeway St., 5th Floor, Suite 500
Boston, MA 02114

Dear Mr. Sencabaugh:

The purpose of this letter is to refer to the Massachusetts Board of Registration in Pharmacy (BORP) 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 BORP, Lynnfield Drug, Inc., dba Freedom Fertility Pharmacy, located at 12 Kent Way, Suite 120F, Byfield, MA 01922-1221 (pharmacy license numbers DS89717 and CS89717).

FDA inspected the firm from February 6, 2018, to February 27, 2018. The FDA investigator was accompanied by three Massachusetts state investigators during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM600767.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. 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 Freedom Fertility 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.

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 use sterile wipes as part of the disinfection program for the aseptic processing areas.

2. The firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area.

Freedom Fertility Pharmacy committed to FDA in its written responses, dated March 15, 2018, and June 6, 2018, to correct the deviations 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 BORP 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 James Mason, Compliance Officer, at 570-262-0519, or by email at james.mason@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: 2018.09.24 12:12:54 -04'00'

Diana Amador-Toro
Program Division Director/District Director
Division of Pharmaceutical Quality Operations I
New Jersey District Office

CC: Dr. Hilary Thibault, PharmD, Pharmacist-in-Charge
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Timothy Wentworth, President and Chief Executive Officer
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