U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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May 7, 2018

Melanie Zimmerman
Executive Secretary
Pennsylvania State Board of Pharmacy
PO Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Zimmerman:

The purpose of this letter is to refer to the Pennsylvania State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor compounding practices observed during an FDA inspection at a pharmacy licensed by the Pennsylvania BOP, GardaRx, LLC, located at 1596 Hancock Avenue, Apollo, PA, 15613-8404 (Pharmacy License #PP481818).

FDA inspected the firm from June 1, 2017, to June 6, 2017. Pennsylvania BOP was informed of the inspection and accompanied the FDA investigator for one day of 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/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm567811.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 investigator reviewed a small sample of records for products compounded by GardaRx, LLC, 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 compounding 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. Exposed particle board on one side of the work surface used to produce non-sterile drug products.

2. The presence of visible dust on the shelf located above the work surface used to produce non-sterile drug products.
3. The presence of visible white powder residue on the balance used to produce non-sterile drug products.

GardaRx, LLC, committed to FDA in its written responses dated June 12, 2017, and September 18, 2017, 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 Pennsylvania 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 K. 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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Date: 2018.05.07 14:54:19 -04'00'

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

cc: GardaRx, LLC
1596 Hancock Avenue,
Apollo, PA, 15613-8404