July 25, 2017

Peter Ragosta
Executive Director
Rhode Island State Board of Pharmacy
3 Capitol Hill, Room 205
Providence, RI 02908-5097

Dear Mr. Ragosta:

The purpose of this letter is to refer to the Rhode Island State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor practices observed during an FDA inspection at a pharmacy licensed by the BOP, Bayview Pharmacy, Inc., located at 3045 Tower Hill Road Unit 3 Saunderstown, RI 02874-1500 (retail pharmacy license number PHA00617).

FDA inspected the firm from August 9, 2016, to August 18, 2016. FDA investigators were accompanied by Rhode Island state investigators for 4 days. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM520806.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 Bayview Pharmacy, 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 its response to the Form FDA 483, dated September 8, 2016, the firm advised FDA that it prepares "both sterile and non-sterile preparations solely on the prescription order of a licensed practitioner."

U.S. Food and Drug Administration
Office of Regulatory Affairs
Division of Pharmaceutical Quality Operations 1
New Jersey District
10 Waterview Blvd.
3rd Floor Parsippany, NJ 07054
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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. Personnel introduced exposed facial skin into the ISO 5 area.

2. The firm used non-sterile disinfectants within the ISO 5 area.

3. The firm failed to demonstrate through appropriate studies that its hood is able to provide adequate protection of the ISO 5 area in which sterile products are processed.

4. Residues remained on the bench surface in a hood after cleaning was performed and while an operator proceeded to production of the next drug product. Additionally, a blender base used to mix dry powders was observed to have white powder residue in the crevices and a containment hood plenum/duct was observed with buildup of powder residues. Finally, investigators observed that an operator's lab coat was soiled in the front and on the sleeves.

Bayview Pharmacy, Inc., committed to FDA in its response to the Form FDA 483, dated September 8, 2016, and February 6, 2017, to correct the deviations in the Form FDA 483, and submitted documentation in support of their 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 Rhode Island State BOP for follow up to ensure appropriate corrective action is taken. In your review of the firm's next routine smoke studies, we recommend that you evaluate whether the smoke plume is adequate to allow for the assessment of unidirectional airflow while personnel are processing in the ISO 5 area. In addition, we recommend that you evaluate if the firm has simulated their more complex manipulations, such as removing and replacing rubber stoppers and aluminum seals, in their next routine smoke studies.

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 Davis, Compliance Officer, at (860) 240-4289 ex. 25, or by email at maya.davis@fda.hhs.gov.

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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=13000011579, cn=Diana Amador-toro -S
Date: 2017.07.26 14:20:43 -04'00'

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

CC: Ryan D. Dyer, Pharmacist and Owner
Bayview Pharmacy, Inc.
3045 Tower Hill Road, Unit 3
Saunderstown, RI 02874-1500