U.S. FOOD & DRUG
ADMINISTRATION

PHILADELPHIA DISTRICT

U.S. CUSTOMHOUSE
2ND AND CHESTNUT STREETS
ROOM 900
PHILADELPHIA, PA 19106
TELEPHONE: 215-597-4390

**CERTIFIED MAIL**
**RETRUN RECEIPT REQUESTED**

May 5, 2017

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 sterile practices observed during an FDA inspection at a pharmacy licensed by the Pennsylvania BOP, Pentec Health, Inc., located at 4 Creek Parkway, Boothwyn, PA 19061-3132 (pharmacy license # PP413743L).

FDA inspected the firm from August 8, 2016, to August 11, 2016. The Pennsylvania BOP was informed of the inspection but did not accompany FDA investigators during the inspection. No Form FDA 483 was issued at the close of the inspection. 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 Pentec Health 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 FDA's post-inspection evaluation of the evidence collected during the August 2016 inspection, FDA identified a deviation from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm used a non-sterile disinfectant to disinfect the ISO 5 area where they produce sterile drug products.

In a telephone conference call held on March 14, 2017, Pentec Health committed to FDA to correct the deviation identified by FDA. In addition, the deviation identified appears 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 Robin M. Rivers, Compliance Officer, at 215-717-3076, or by email at robin.rivers@fda.hhs.gov.

Sincerely,

Anne Johnson.

Anne E. Johnson
District Director
Philadelphia District