



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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Parsippany, NJ 07054
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March 12, 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 notify the Pennsylvania State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not intend to take further action with regard to an inspection of a pharmacy licensed by the Pennsylvania BOP, Pentec Health, Inc., located at 4 Creek Parkway, Suite A, Boothwyn, PA 19061-3132 (License #: PP413743L).

FDA inspected the firm from August 30, 2017 to September 8, 2017. The Pennsylvania BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. No Form FDA 483 was issued to the firm.

During the inspection, the FDA investigator 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, which is consistent with traditional pharmacy practice. After review of the records, FDA does not intend to take further action with regard to the findings of this inspection at this time and believes that the firm's pharmacy practice can be appropriately overseen by the State. 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 Yvette I. Johnson, Compliance Officer by phone at (215) 717-3077, or by email at yvette.johnson@fda.hhs.gov.

~~Office of Pharmaceutical Quality Operations, Division of Pharmaceutical Quality Operations I~~

New England District Office: One Montvale Avenue, 4th Floor Stoneham, MA 02180-3500 T- (781) 587-7500 F- (781) 587-7556
New York District Office: 158-15 Liberty Ave Jamaica, NY 11433 T-(718) 340-7000 F-(718) 662-5661
Philadelphia District Office: US Custom House Room 900, 200 Chestnut St. Philadelphia, PA 19106 T- (215) 597-4390 F-(215) 597-4660
Baltimore District Office: 6000 Metro Drive, Suite 101 Baltimore, MD 21215 T-410-779-5455 F- 410-779-5407

Sincerely,

Diana
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Digitally signed by Diana Amador-
toro -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
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Date: 2018.03.12 13:50:10 -04'00'

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

cc: Pentec Health, Inc.
4 Creek Parkway, Suite A
Boothwyn, PA 19061-3132