



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
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www.fda.gov

April 9, 2020

Daniel Martins
Executive Vice President
Pentec Health, Inc.
9 Creek Parkway
Boothwyn, PA 19061

Dear Mr. Martins:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Pentec Health, Inc., located at 9 Creek Parkway, Boothwyn, PA 19061, from May 14, 2019, to May 30, 2019, by the U.S. Food and Drug Administration (FDA).

We acknowledge that your firm has closed as of November 18, 2019 and is no longer operational.

If you decide to resume operations in the future, you are expected to take all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations, and you should notify this office 15 days prior to resuming production of any drug products.

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

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 Customs 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

If there is any question about the released information, please contact Yvette Johnson, Compliance Officer at Yvette.Johnson@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,
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Date: 2020.04.09 10:39:21 -04'00'

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

Enclosure: EIR

Cc: Pennsylvania Department of Health (cover letter only)
Theresa Ritchie, R.Ph., Pharmacist Program Manager
Drug, Device, and Cosmetic Program
555 Walnut Street – 7th Floor – Suite 701
Harrisburg, PA 17101

Pennsylvania State Board of Pharmacy (cover letter only)
Melanie Zimmerman, Executive Secretary
PO Box 2649
Harrisburg, PA 17105