



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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August 31, 2018

Daniel Martins, VP Outsourcing Facility
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 February 5, 2018, to February 23, 2018, by the U.S. Food and Drug Administration (FDA).

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.

If there is any question about the released information, please contact Yvette Johnson, Compliance Officer, by email at Yvette.Johnson@fda.hhs.gov or by phone at (215) 717-3077.

Sincerely,

Yvette Johnson -S

Digitally signed by Yvette Johnson -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Yvette Johnson -S,
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Yvette Johnson, Compliance Officer
Philadelphia District/PHRM1-CB

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