



**FDA U.S. FOOD & DRUG
ADMINISTRATION**

OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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www.fda.gov

March 12, 2018

Mr. Joseph Cosgrove
Chairman, President, and CEO
Pentec Health, Inc.
4 Creek Parkway, Suite A
Boothwyn, PA 19061-3132

Dear Mr. Cosgrove:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Pentec Health, Inc., located at 4 Creek Parkway, Suite A, Boothwyn, PA 19061-3132, from August 30, 2017 to September 8, 2017, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Pennsylvania State Board of Pharmacy for follow up.

When the Agency considers an inspection to be “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 I. Johnson, Compliance Officer by phone at (215) 717-3077, or by email at yvette.johnson@fda.hhs.gov.

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
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Date: 2018.03.09 15:13:15 -05'00'

Yvette Johnson
Compliance Officer – PHRM1-CB
Philadelphia District Office

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

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