

PHILADELPHIA DISTRICT

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

CERTIFIED MAIL RETURN RECEIPT REQUESTED

May 5, 2017

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

FEI#: 3006489293

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 8, 2016, to August 11, 2016, 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 and we have enclosed a copy with this letter. 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.

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If there is any question about the released information, please contact Robin M. Rivers, Compliance Officer, at 215-717-3076, or by email at robin.rivers@fda.hhs.gov.

Sincerely,

Anne E. Johnson District Director Philadelphia District

Enclosure:

- > Establishment Inspection Report, dated August 8, 2016 to August 11, 2016
- > State Referral Letter, dated may 5, 2017

cc: Pennsylvania State Board of Pharmacy (cover letter only)