



U.S. Food and Drug Administration  
Division of Pharmaceutical Quality Operations I  
10 Waterview Blvd, 3<sup>rd</sup> FL  
Parsippany, NJ 07054  
Telephone: (973) 331-4900  
FAX: (973) 331-4969  
[www.fda.gov](http://www.fda.gov)

October 3, 2019

VIA UNITED PARCEL SERVICE

Melanie Zimmerman, RPh  
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, Insight Pharmaceutical Solutions, LLC, dba Insight Pharmacy, located at 700 E Township Line Road, Suite LL2, Havertown, PA 19083-5733 (License #: PP482437).

FDA inspected the firm from January 15, 2019, to January 17, 2019. Inspectors from the Pennsylvania BOP accompanied 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 Insight Pharmacy 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 CDR James Mason, via email at [james.mason@fda.hhs.gov](mailto:james.mason@fda.hhs.gov) or by phone at (570) 262-0519.

Sincerely,

Craig W. Swanson -S

Digitally signed by Craig W. Swanson -S  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,  
0.9.2342.19200300.100.1.1=1300092363, cn=Craig W. Swanson -S  
Date: 2019.10.03 13:35:15 -04'00'

Craig Swanson  
For Diana Amador-Toro  
Program Division Director/District Director  
OPQO Division I/New Jersey District Office

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