



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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Wednesday, May 9, 2018

Melanie Zimmerman, Executive Secretary
Pennsylvania State Board of Pharmacy
P.O. 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, Walter's Pharmacy, Inc., located at 401 N 17th Street, Allentown, PA 18104-5034 (License #: PP412814L).

FDA inspected the firm from October 16, 2017, to October 25, 2017. The Pennsylvania BOP was informed of the inspection, but did not accompany FDA investigators 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 Walter's Pharmacy, Inc. 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, 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. In addition, please notify FDA if you become aware of this firm resuming production of drug products intended to be sterile.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Ernest Bizjak, Compliance Officer, at 301-796-4081, or by email at Ernest.Bizjak@fda.hhs.gov.

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: 2018.05.09 10:16:40 -0400'

For
Diana Amador Toro
Division Director/OPQ Division 1
New Jersey District Office

Cc: Walter's Pharmacy, Inc.
401 N 17th St
Allentown, PA 18104-5034

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

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