



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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December 18, 2018

Kimberly A. Leonard
Executive Secretary
New York State Board of Pharmacy
89 Washington Ave, 2nd Floor W
Albany, NY 12234-1000

Dear Ms. Leonard:

The purpose of this letter is to notify the New York 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 New York State BOP, Fallon Wellness Pharmacy, LLC, located at 1057 Troy-Schenectady Road, Latham, New York, 12110-1002 (License #: 026112).

FDA inspected the firm from November 1, 2016 to December 6, 2016. The New York State BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at:

<https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAElectronicReadingRoom/UCM542614.pdf>

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Fallon Wellness Pharmacy, LLC 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. 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 CDR James Mason via email at james.mason@fda.hhs.gov or by phone at (570) 262-0519.

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

Sincerely,

Diana
Amador-
toro -S

Digitally signed by Diana Amador-toro -S
DN: cn=S, ou=U.S. Government, ou=HHS,
ou=FDA, ou=People,
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Date: 2018.12.18 14:48:24 -05'00'

Diana Amador-Toro
Program Division Director
OPQO Division 1
New Jersey District Office

Cc: Fallon Wellness Pharmacy, LLC
1057 Troy Schenectady Rd
Latham, NY 12110-1002