



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
Telephone: (973) 331-4900
Fax: (973) 331-4969
www.fda.gov

June 6, 2019

Paul W. Thompson, Interim Executive Secretary
New York State Board of Pharmacy
89 Washington Ave, 2nd Floor W
Albany, NY 12234-1000

FEI #3012729025

Dear Mr. Thompson:

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 previously licensed by the New York State BOP, Magellan Rx Pharmacy, LLC, located at 31-75 23rd Street, Suite 410, Astoria, NY 11106-4134 (License Registration No. 027378: Status: discontinued). On February 21, 2019, FDA was notified of the closure of this facility, effective December 31, 2018, and that the Astoria, NY, location for Magellan Rx Pharmacy, LLC, relinquished its pharmacy license when the facility closed.

FDA inspected the firm from July 26, 2018, to August 9, 2018. The New York State BOP was informed of the inspection and accompanied the FDA investigator during the first day of the inspection. A Form FDA 483 was not issued to the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Magellan Rx Pharmacy, LLC and determined, based on this sample, that this firm appeared 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. Should the firm re-open in the future, FDA believes that the firm's pharmacy practice can be appropriately overseen by the State. Additionally, if the firm does re-open, please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at that facility, or if you observe any practices that concern you or that could be violations of Federal law.

Office of Pharmaceutical Quality Operations

Pharmaceutical Division I
10 Waterview Blvd. 3rd Floor
Parsippany, NJ 07054
Telephone: (973) 331-4900

Pharmaceutical Division II
4040 N. Central Expressway, Suite 300
Dallas, TX 75204
Telephone: (214) 253-5200

Pharmaceutical Division III
300 River Place, Suite 5900
Detroit, MI 48207
Telephone: (313) 393-8100

Pharmaceutical Division IV
19701 Fairchild Rd.
Irvine, CA 92612
Telephone: (949) 797-1063

If you have any questions, contact Compliance Officer Juan Jimenez at juan.jimenez@fda.hhs.gov or 518-453-2314 X-1014.

Diana
Amador-toro -
S



Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=130001
1579, cn=Diana Amador-toro -S
Date: 2019.06.06 16:27:44 -04'00'

Diana Amador-Toro
Program Division Director/District Director
U.S. Food and Drug Administration
OPQO Division I /New Jersey District