

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

February 26, 2019

## **VIA UPS OVERNIGHT**

David M. Miller, R.Ph Owner/President Millers of Wyckoff, Inc. 678 Wyckoff Avenue Wyckoff, NJ 07481

Dear Mr. Miller:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspections conducted at your facility, Millers of Wyckoff, Inc, located at 678 Wyckoff Avenue, Wyckoff, NJ 07481, from June 29, 2015 to July 16, 2015 and April 4, 2017, to May 18, 2017, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the New Jersey 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.

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.

If there is any question about the released information, please Barbara Wilimczyk-Macri, Compliance Officer, at 973-331-4951 or by email at barbara.wilimczyk@fda.hhs.gov.

Sincerely,

Diana Amador-Toro Program Division Director Office of Pharmaceutical Quality Operations Division I

Enclosure: EIR, SRL

Cc: New Jersey State Board of Pharmacy (cover letter only)

Attention: Anthony Rubinaccio, Executive Director

PO Box 45013, Newark, NJ 07101

Office of Pharmaceutical Quality Operations