

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

April 25, 2019

Alfonse Muto, Sr.
Owner
Pine Pharmacy and Home Care Products Center, Inc.
5110 Main Street
Williamsville, NY 14221

Dear Mr. Muto:

We are enclosing copies of the Establishment Inspection Reports (EIRs) for the inspections conducted at your facility, Pine Pharmacy and Home Care Products Center, Inc., located at 5110 Main Street, Williamsville, NY 14221, from March 30, 2016, to April 18, 2016, and from December 10, 2013, to December 16, 2013, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the New York 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 contact CDR James Mason, via email at <u>james.mason@fda.hhs.gov</u> or by phone at (570) 262-0519.

Sincerely,
Stephanie T.
Durso -S

Digitally signed by Stephanie T. Durso -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300194209, cn=Stephanie T. Durso -S Date: 2019.04.25 14:29:05 -04'00'

Stephanie Durso Director Compliance Branch Office of Pharmaceutical Quality Operations – Division I New Jersey District Office

Office of Pharmaceutical Quality Operations