



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
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May 7, 2018

Martin J. Garda, RPh
President and Owner
GardaRx, LLC
1596 Hancock Avenue
Apollo, PA 15613-8404

Dear Mr. Garda:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, GardaRx, LLC, located at 1596 Hancock Avenue, Apollo, PA, 15613-8404, from June 1, 2017, to June 6, 2017, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Pennsylvania State Board of Pharmacy for follow up.

When the Agency considers an inspection to be “closed” under 21 CFR. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment and we have enclosed a copy with this letter.

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 CFR 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 Liatte K. Closs, Compliance Officer, at (973) 331-4933.

Sincerely,

Yvette Johnson -S

Digitally signed by Yvette Johnson -S
DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, cn=Yvette Johnson -S,
0.9.2342.19200300.100.1.1=1300040228
Date: 2018.05.07 14:32:53 -0400

Yvette Johnson
Acting Compliance Branch Director/OPQ Division 1
New Jersey District Office

Enclosure: EIR, SRL

cc: Pennsylvania State Board of Pharmacy (cover letter only)
One Penn Center, 2601 N. 3rd Street
Harrisburg, PA 17110

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
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