

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

July 7, 2020

VIA ELECTRONIC MAIL

Gary Hanley Chief Executive Officer SterRx, LLC. 141 Idaho Avenue Plattsburgh, NY 12903-3987

Dear Mr. Hanley,

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, SterRx, LLC., located at 141 Idaho Avenue, from June 3, 2019, to June 7, 2019, by the U.S. Food and Drug Administration (FDA).

When the Agency concludes that an inspection is "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 you have any questions contact Compliance Officer Juan Jimenez at juan.jimenez@fda.hhs.gov or 518-453-2314 X-1014. Please identify your communications with FEI: 3010840309.

Stephanie T. Durso -S Digitally signed by Stephanie T. Durso -S DN: c=US, o=U.S. Government, ou=HHS, ou=FoDA, ou=People, 0.9.2342.19200300.100.1.1=1300194209, cn=Stephanie T. Durso -S Date: 2020.07.07 10:23:40 -04'00'

Stephanie Durso Director Compliance Branch U.S. Food and Drug Administration OPQO Division I / New Jersey District

Office of Pharmaceutical Quality Operations