

U.S. Food and Drug Administration Division of Pharmaceutical Quality Operations III 300 River Place, Suite 5900 Detroit, MI 48207

Telephone: (313) 393-8100 Fax: (313) 393-8139 www.fda.gov

September 12, 2019

UPS NEXT DAY SIGNATURE REQUIRED

Raymond R. Carlson, RPh Owner/Pharmacist RC Compounding Services, LLC 3030 Center Road Poland, OH 44514

Dear Mr. Carlson:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, RC Compounding Services, LLC, located at 3030 Center Road, Poland, OH 44514, from February 12, 2018, to February 16, 2018, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the State of Ohio 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.

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 Nicholas Lyons at (312) 596-4220 or by email at: ORAPHARM3 RESPONSES@FDA.HHS.GOV.

Sincerely,

Nicholas F. Lyons - S

Digitally signed by Nicholas F. Lyons - S

DN: C=US, G=US. Government, ou=HHS, ou=FDA, ou=People, og_2542+1290300.100.11=1300120033, cn=Nicholas F. Lyons - S

Date: 2019.09.12 11:46:12-05'00'

Nicholas F. Lyons Director Compliance Branch Division of Pharmaceutical Quality Operations III

Enclosures: Redacted 1st party EIR, State Referral Letter