

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

July 11, 2019

<u>UPS NEXT DAY</u> SIGNATURE REQUIRED

Jennifer Rickner Pharmacist In Charge Kohll's Compounding 620 N. 114th Street Omaha, NE 68154-1571

Dear Ms. Rickner:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Essential Pharmacy Compounding (currently known as Kohll's Compounding), located at 620 N. 114th Street, Omaha, NE 68154-1571, from July 10, 2017, to July 27, 2017, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit 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 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 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 Nicholas Lyons at (312) 596-4220 or by email at: ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Nicholas F.

ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300120033, cn=Nicholas F. Lyons - 5 Date: 2019.07.11 09:22:25 -05'00'

Lyons -S

Nicholas F. Lyons Compliance Director

Division of Pharmaceutical Quality Operations III

Digitally signed by Nicholas F. Lyons -S

DN: c=US, o=U.S. Government, ou=HHS,

Enclosures: EIR, State Referral Letter