

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

April 10, 2019

UPS NEXT DAY SIGNATURE REQUIRED

Brent Ferguson Pharmacist-in-Charge Mayo Clinic Pharmacy 21 2nd St. SW Rochester, MN 55905-0001

Dear Mr. Ferguson:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Mayo Clinic Pharmacy, located at 21 Second St SW, Brackenridge Building, Lower Level, Rochester, Minnesota 55902, from August 6, 2018, to August 15, 2018, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Minnesota 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 Brett R. Havranek, Compliance Officer, at (913)-495-5189, or by email at ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

-S

Nicholas F. Lyons Digitally signed by Nicholas F. Lyons -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=Pocal-0.9.2342.19200300.100.1.1=1300120033, cn=Nicholas F. Lyons -S Date: 2019.04.10 10:28:39 -05'00'

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