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

October 21, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Matthew J. Buderer
Owner
Buderer Drug Company
26611 Dixie Highway, Suite 119
Perrysburg, OH 43551-1765

Dear Mr. Buderer:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Buderer Drug Company, 38530 Chester Rd Ste 400, Avon, OH 44011-4048, from February 7, 2019, to February 14, 2019, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Ohio State 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 Tina Pawlowski, Compliance Officer, at (313) 393-8217 or by email at: ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Nicholas F. Lyons -S

Digitally signed by Nicholas F. Lyons -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300120033, cn=Nicholas F. Lyons -S
Date: 2019.10.21 12:49:01 -05'00'

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