U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OPQO DIVISION OF PHARMACEUTICAL QUALITY OPS 3

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
300 River Place, Suite 5900
Detroit, MI 48207
Telephone: (313) 393-8100
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www.fda.gov

June 13, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Stephen C. Morton
CEO
Morton Drug Company dba Morton LTC
201 E. Bell Street
Neenah, WI 54956-5096

Dear Mr. Morton:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspections conducted at your facility, Morton Drug Company dba Morton LTC, located at 201 E. Bell Street, Neenah, WI 54956-5096, from August 27, 2018, to August 31, 2018, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing a copy of the state referral letter (SRL) sent to the Wisconsin Pharmacy Examining Board 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 Brian D. Garthwaite, Ph. D., Compliance Officer, at 612-758-7132 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: 2019.06.13 08:52:46 -05'00'

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