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

June 13, 2019

**UPS NEXT DAY**
**SIGNATURE REQUIRED**

Debra Sybell
Executive Director
Wisconsin Department of Safety and Professional Services
Pharmacy Examining Board
4822 Madison Yards Way
Madison, WI 53708-8366

Dear Ms. Sybell:

The purpose of this letter is to refer to the Wisconsin Department of Safety and Professional Services, Pharmacy Examining Board for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Wisconsin Department of Safety and Professional Services, Morton Drug Company, dba Morton LTC, located at 201 E. Bell Street, Neenah, WI 54956-5096 (Pharmacy license #9299-42).

FDA inspected the firm from August 27, 2018, to August 31, 2018. Wisconsin Department of Safety and Professional Services was informed of the inspection but did not accompany FDA investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm623309.pdf, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, and that contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Morton Drug Company and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes. In a September 21, 2018 response to the Form FDA 483, the firm advised FDA that it "seeks to provide FDA with further assurances that it is committed to providing the highest quality compounded preparations as a Section 503A compounding pharmacy."

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. Material or supplies were not disinfected prior to entering the aseptic processing areas.

2. Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

3. Beta-lactam drugs were produced without providing adequate cleaning of work surfaces to prevent cross-contamination for these products.

Morton Drug Company committed to FDA in its response to the Form FDA 483, to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Wisconsin Department of Safety and Professional Services for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have questions about this letter, please contact Brian D. Garthwaite, Ph.D., Compliance Officer, at 612-758-7132.

Sincerely,

Jeffrey D. Meng -S

Digitally signed by Jeffrey D. Meng -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000367142, cn=Jeffrey D. Meng -S
Date: 2019.06.13 10:24:43 -04'00'

Director of Investigations Branch
Division of Pharmaceutical Quality Operations III

For

Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III

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