U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
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April 10, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Stacey Jassey
President
Minnesota Board of Pharmacy
2829 University Avenue SE, #530
Minneapolis, MN 55414

Dear Ms. Jassey:

The purpose of this letter is to refer to the Minnesota Board of Pharmacy (BOP) 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 Minnesota BOP, Mayo Clinic Pharmacy, located at 21 Second St SW, Brackenridge Building, Lower Level, Rochester, Minnesota 55902 (Pharmacy License #260408; Expires 06/30/2019).

FDA inspected the firm from August 6, 2018, to August 15, 2018. FDA investigators were accompanied by Minnesota State Pharmacy Surveyors for 5 days. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM626339.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, which 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 Mayo Clinic Pharmacy 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.

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. Failure to conduct an adequate investigation or an assessment of product quality after the firm detected microbial contamination within an ISO 5 aseptic processing area.

2. Non-microbial contamination on equipment adjacent to an ISO 5 aseptic processing area (e.g., rust on the wheels of a cart inside an ISO 7 classified clean room, adjacent to an ISO 5 aseptic processing area).

3. Failure to use sterile cleaning agents in the ISO 5 aseptic processing areas.

4. Failure to use a sporicidal cleaning agent in a manner sufficient to achieve adequate disinfection.

Mayo Clinic Pharmacy committed to FDA in its response to the Form FDA 483, received 08/30/2018, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable. Per the firm's request, an unredacted copy of their response to the Form FDA 483 (excluding attachments) is available in the ORA FOIA Electronic Reading Room at https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/oraelectronicreadingroom/default.htm.

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 Minnesota BOP 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 additional questions, please contact Brett R. Havranek, Compliance Officer, at (913)-495-5189, or by email at ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Nicholas F. Lyons -S

Digitally signed by Nicholas F. Lyons -S
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Date: 2019.04.10 09:10:49 -05'00'

Nicholas F. Lyons
Compliance Director
Division of Pharmaceutical Quality Operations III
On behalf of
Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III

Cc: Mayo Clinic Pharmacy
21 Second Street SW
Brackenridge Building
Rochester, Minnesota 55902