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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June 13, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Cheryl Wykoff Pezon
Director
Michigan Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Michigan State Board of Pharmacy
611 W. Ottawa, 3rd Foor, PO Box 30670
Lansing, MI 48909-8170

Dear Ms. Pezon:

The purpose of this letter is to refer to the Michigan State 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 Michigan BOP, Michigan Medicine, located at 1500 E. Medical Center Drive, Ann Arbor, MI 48109 (Pharmacy License #5301011375).

FDA inspected the firm from December 3, 2018, to December 14, 2018. An FDA investigator was accompanied by a Michigan State investigator for one day. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/123527/download 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 investigator reviewed a small sample of records for products compounded by Michigan Medicine 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 the response to the Form FDA 483, dated January 8, 2019, the firm advised FDA that it "continues to operate as a 503A compounding pharmacy, licensed by the State of Michigan, under the prevailing standards of USP <797>."

During the inspection, the FDA investigator 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. Materials and supplies were not disinfected prior to entering the aseptic processing area.

2. The firm's cleaning and disinfection practices were inadequate.

3. Personnel engaged in aseptic processing were observed with exposed skin within the ISO 5 hood.

4. Personnel were observed moving quickly within the ISO 5 hood such that unidirectional airflow may have been disrupted.

Michigan Medicine committed to FDA in its response to the Form FDA 483 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.

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 Michigan State 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 Tina Pawlowski, Compliance Officer, at (313) 393-8217 or by email at ORAPHARM3_RESPONSES@fda.hhs.gov.

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 14:30:32 -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: Stanley S. Kent, R.Ph.
Chief Pharmacy Officer
Michigan Medicine
1500 E. Medical Center Drive
Ann Arbor, MI 48109-5008