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

November 1, 2018

UPS NEXT DAY
SIGNATURE REQUIRED

Cheryl Wykoff Pezon
Michigan State Board of Pharmacy
Bureau of Professional Licensing/Licensing Division
611 W. Ottawa, 3rd Floor
P.O. 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, Diversified Pharmacy, Inc., dba University Compounding Pharmacy, located at 6054 Livernois Road, Troy, MI 48098 (Pharmacy License #5301007150).

FDA inspected the firm from June 5, 2017, to June 19, 2017. Michigan BOP 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/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM570871.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 Diversified Pharmacy, Inc., dba University Compounding 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:

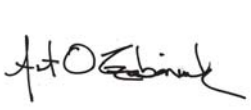
1. A large patch of white residue was observed on the HEPA filter grate of an ISO 5 laminar flow hood during aseptic processing of drug products.
2. Smoke studies were not performed under actual production conditions, including all equipment used by the firm during sterile drug production.
3. Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of:
    a. glassware and stainless steel utensils used for non-sterile drug processing
    b. containers used to reduce drug substances from bulk stock

Diversified Pharmacy, Inc., dba University Compounding Pharmacy, committed to FDA in its response to the Form FDA 483, received June 30, 2017, 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 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,



Digitally signed by Art O. Czabaniuk -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300174393, cn=Art O. Czabaniuk -S
Date: 2018.11.01 14:12:16 -04'00'

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

cc: Joseph J. McCloskey
Owner
Diversified Pharmacy, Inc., dba
University Compounding Pharmacy
6054 Livernois Road
Troy, MI 48098