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 14, 2018

UPS NEXT DAY

Shelly Edgerton
Executive Director
Michigan State Board of Pharmacy
611 W. Ottawa
P.O. Box 30004
Lansing, MI 48909

Dear Ms. Edgerton:

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 production practices observed during an FDA inspection at a pharmacy licensed by the Michigan BOP, Keystone Pharmacy, located at 4021 Cascade Road SE, Ste. 50 Grand Rapids, MI 49546 (pharmacy license number 5301007431).

FDA inspected the firm from October 17, 2017, to November 3, 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/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm585292.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 Keystone 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 practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm produced highly potent drugs without providing adequate segregation and cleaning of utensils to prevent cross contamination.

Keystone Pharmacy committed in a November 20, 2017, 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, 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 Brian D. Garthwaite, Ph. D., Compliance Officer, at 612-758-7132 or by email at: Brian.Garthwaite@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: 2018.06.14 12:46:30 -04'00'

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

cc: David J. Miller, R.Ph., Ph.D.
Co-owner
Keystone Pharmacy
4021 Cascade Road SE, Ste.50
Grand Rapids, MI 49546