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U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
Telephone: (313) 393-8100
Fax: (313) 393-8139
www.fda.gov

October 22, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Cody C. Wiberg, Pharm.D.
Executive Director
Minnesota Board of Pharmacy
2829 University Avenue SE, Suite 530
Minneapolis, MN 55414-3251

Dear Dr. Wiberg:

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 practices observed during an FDA inspection at a pharmacy licensed by the Minnesota BOP, W & C Apothecary dba The Apothecary, located at 165 19th Street South, Suite 102, Sartell, MN 56377 (License# 263665).

FDA inspected the firm from July 23, 2018, to July 30, 2018. The FDA investigator was accompanied by a Minnesota BOP Pharmacy Surveyor for the entirety of the inspection. 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/131389/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 W & C Apothecary dba The Apothecary 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 an August 20, 2018, response to the Form FDA 483 the firm advised FDA that it prepares "compounded prescriptions only for individually identified patients upon receipt of a patient-specific order."

During the inspection, the FDA investigator observed deviations from appropriate non-sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm produced beta-lactam drugs, hazardous, and highly potent drugs without performing adequate cleaning of work surfaces and cleaning of utensils.

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W & C Apothecary dba The Apothecary 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 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 Brian Garthwaite, Ph.D., Compliance Officer, at 612-758-7132.

Sincerely,

Nicholas F. Lyons -S

Digitally signed by Nicholas F. Lyons -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300120033, cn=Nicholas F. Lyons -S
Date: 2019.10.22 16:13:15 -05'00'

Nicholas F. Lyons
Director of Compliance
Division of Pharmaceutical Quality Operations III

For

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

cc: Stephen G. Anderson, R.Ph.
Owner
W & C Apothecary dba The Apothecary
165 19th Street South, Suite 102
Sartell, MN 56377-2567