U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
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www.fda.gov

April 3, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Dr. Yashwant Amin
Director of Drug Compliance
Division of Professional Regulation
100 W Randolph St. Suite 9-300
Chicago, Illinois 60601

Dear Dr. Amin:

The purpose of this letter is to refer to the Illinois State 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 Illinois BOP, WellRx LLC, dba HomeRx LLC, located at 200 E Willow Ave Ste 100, Wheaton, IL 60187 (Licensed Pharmacy, #054020427, and Licensed Controlled Substance, #32*****31).

FDA inspected the firm from October 2, 2017, to November 13, 2017. Illinois BOP was informed of the inspection but did not accompany the FDA investigator during 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/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm590712.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 investigator reviewed a small sample of records for products compounded by WellRx LLC, dba HomeRx LLC, 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.

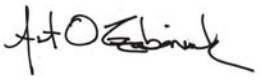
During the inspection, the FDA investigator observed a deviation from appropriate standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm used non-pharmaceutical grade water to produce human drug products.

WellRx LLC, dba HomeRx LLC, committed to FDA in its response to the Form FDA 483, to correct the deviation in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviation identified appears 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 Illinois 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. It is our understanding that the firm does not currently perform sterile compounding. Please notify FDA if you become aware of this firm resuming production of sterile drug products.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Russell Riley, Compliance Officer, at (630) 323-2763 ext. 101, or by email at Russell.Riley@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: 2019.04.03 12:25:30 -04'00'

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

cc: Ambreen Jafri
WellRx LLC dba HomeRx LLC
200 E Willow Ave Ste 100
Wheaton, IL 60187