U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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June 19, 2018

**UPS NEX DAY**

Robert Gerton
Illinois Department of Financial and Professional Regulation
Division of Professional Regulation – State Board of Pharmacy
Pharmacy Board Liaison
320 W Washington, 3rd Floor
Springfield, IL 62786

Dear Mr. Gerton:

The purpose of this letter is to refer to the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy (IDFPR) 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 IDFPR, Carepoint Healthcare LLC, dba Carepoint Pharmacy, located at 9 East Commerce Drive, Schaumburg, IL 60173-5302 (Pharmacy license #054018043).

FDA inspected the firm from July 17, 2017, to August 24, 2017. The IDFPR 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/UCM575837.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 Carepoint 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 technician donned sterile gloves by touching the outside of the gloves with a bare hand and then proceeded to aseptic production; a technician with exposed facial skin leaned into the ISO 5 laminar air flow hood during aseptic production; a technician failed to disinfect items when transferring them from the cleanroom into the ISO 5 area. Our investigators also observed that a technician donned sterile gloves that were placed next to the sink when a technician was washing their hands.

2. The TPN machine and balance in the ISO 5 area were not routinely disinfected prior to production.

3. An open package of sterile wipes was exposed to the ISO 7 environment, and these wipes were used to clean the ISO 5 area.

4. The firm did not use a sporicidal agent to disinfect the aseptic process area.

5. Media fills were not performed under the most challenging or stressful conditions.

Carepoint Pharmacy committed to FDA in its responses to the Form FDA 483 dated September 5, 2017, and January 25, 2018, to correct the deviations 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 IDFPR 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
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Date: 2018.06.19 12:22:35 -04'00'

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

cc: Dr. Bhavesh R. Patel, Pharm. D.
CEO and Owner
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