U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OPQO DIVISION OF PHARMACEUTICAL QUALITY OPS 3

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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May 5, 2020

UPS NEXT DAY
SIGNATURE REQUIRED

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

Dear Dr. Amin:

The purpose of this letter is to refer to the Illinois Department of Financial and Professional Regulation (IDFPR), Division of Professional Regulation, Illinois 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 IDFPR, Techni Med Inc. dba The Compounder, located at 340 Marshall Avenue, Unit 100, Aurora, IL 60506-5649 (Pharmacy license #054008872).

FDA inspected the firm from September 23 to October 10, 2019. 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 the investigator's observations from the inspection can be found at https://www.fda.gov/media/133590/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 Techni Med Inc. dba The Compounder 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.

Additionally, during the inspection, the FDA investigator observed deviations from 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. Non-microbial residue was observed on a garbage can and the floor in the ISO 7 cleanroom, and on a garbage can in the ISO 8 anteroom.

2. Adequate product evaluation and remedial action were not taken when actionable microbial contamination was found adjacent to the ISO 5 aseptic processing area.

3. A non-pharmaceutical grade ingredient was used as a component of non-sterile pharmaceutical products.

4. Non-sterile cleaning wipes were used to clean the ISO 5 hoods.

Techni Med Inc. dba The Compounder committed to correcting the deviations and provided documentation in support of the corrective actions in October 21, 2019, and February 13, 2020, responses to the Form FDA 483. The firm also committed to endotoxin testing of active pharmaceutical ingredients, endotoxin testing of samples of intrathecal preparations, and validation of testing laboratories used for potency, sterility, and endotoxin testing. 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 overseen by the State. Therefore, FDA is referring this matter to the Illinois State 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,

Digitally signed by Art O. Czabaniuk -S
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Date: 2020.05.05 12:50:43 -04'00'

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

cc: Lawrence J. Frieders
Owner and Pharmacist in Charge
Techni Med, Inc. dba The Compounder
340 Marshall Avenue, Unit 100
Aurora, IL 60506-5649