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

U.S. Food and Drug Administration
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July 10, 2017

Steven W. Schierholt, Esq.
Executive Director
Ohio State Board of Pharmacy
77 S. High St.
Columbus, OH 43215

RE: FDA Inspection of Cincinnati Specialty Pharmacy

Dear Mr. Schierholt:

The Food and Drug Administration (FDA) is referring to the Ohio State Board of Pharmacy (BOP) for appropriate follow up, our concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Ohio BOP, Cincinnati Specialty Pharmacy, LLC, 7731 Cox Lane, West Chester, OH 45069 (Pharmacy, License# NRP.022294500-03).

FDA inspected the firm from September 6, 2016, to September 26, 2016. The Ohio 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/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM524166.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. 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 Cincinnati Specialty Pharmacy, 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 investigators noted the firm's calculation errors. Specifically, the firm released two finished compounded products to patients that were ten times sub-potent for liothyronine (T3) in T3/T4 compounded product than the amount prescribed by the physicians of the patients.

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 Ohio State BOP for appropriate follow up. 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 Tina Pawlowski, Compliance Officer, at 313-393-8217 or by email at tina.pawlowski@fda.hhs.gov.

Sincerely,

Art O. Czabaniuk -S

Digitally signed by Art O. Czabaniuk -S
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Art O. Czabaniuk

Program Division Director
Division of Pharmaceutical Quality Operations III