FDA 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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October 2, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Darren Covington, Director
Indiana Professional Licensing Agency
402 W. Washington, St., room W072
Indianapolis, IN 46204

Dear Mr. Covington:

The purpose of this letter is to notify the State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not intend to take further action regarding an inspection of a pharmacy licensed by the Indiana BOP, Crowder's Institutional Pharmacy LLC., dba Crowder's Long-Term Care Pharmacy (License #: 60004400A).

FDA inspected the firm from March 4-7, 2019. The Indiana BOP was informed of the inspection but did not accompany FDA investigators during the inspection. No Form FDA 483 was issued to the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Crowder's Institutional Pharmacy LLC., dba Crowder's Long-Term Care 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, which is consistent with traditional pharmacy practice.

After review of the records, FDA does not intend to take further action regarding the findings of this inspection at this time and believes that the firm's pharmacy practice can be appropriately overseen by the State. 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 Eric Mueller at 402-331-8536 ext. 101 or by email at ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Digitally signed by Art O. Czabaniuk -S
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Date: 2019.10.02 13:23:42 -04'00'

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