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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June 28, 2017

Alexandra Blasi
Executive Secretary
Kansas State Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

Dear Ms. Blasi:

The purpose of this letter is to notify the Kansas State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration does not intend to take further action with regard to an inspection of a pharmacy licensed by the Kansas BOP, O'Brien Pharmacy, located at 5453 W. 61st Place, Mission, KS 66205 (License #2-10030).

FDA inspected the firm from September 23, 2016, to October 13, 2016. Investigators from the Kansas BOP accompanied FDA investigators for part of 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 O'Brien 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.

FDA does not intend to take further action with regard to 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, Regulatory officer, at 402 331-8536 or by email at Eric.Mueller@fda.hhs.gov.

Sincerely,

Art O. Czabaniuk -S

Digitally signed by Art O. Czabaniuk -S
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Art O. Czabaniuk
Division Director
Division of Pharmaceutical Quality Operations III