DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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VIA UPS

March 6, 2017

Robert Kendall
Executive Director
Indiana State Board of Pharmacy
402 West Washington Street, Room W072
Indianapolis, Indiana, 46204

Dear Mr. Kendall:

The purpose of this letter is to refer to the Indiana 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 Indiana BOP, Pharmakon Long Term Care Pharmacy, Inc., located at 801 Congressional Blvd, Suite 200A, Carmel, IN, 46032 (Pharmacy License #054016192).

FDA inspected the firm from April 18, 2016, to May 11, 2016. Indiana BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at:
http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm506297.pdf.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Pharmakon Long Term Care Pharmacy, Inc., and determined, based on this sample, that this firm appeared 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. Specifically, the firm uses non-sterile cleaning agents for cleaning and disinfecting the aseptic processing areas. In addition, the firm failed to monitor the pressure differentials between the ISO 6 classified area and unclassified area. Furthermore, the operations related to the production of beta-lactam drug products are not adequately segregated from the production of non-beta lactam drug products.

The investigators also noted that between January 2016 and April, 2016 the firm documented over eighty complaints. Complaints were received for issues which included patients receiving the incorrect medication, dose, or dosage form and medications without directions or the correct packaging. In several instances, prescriptions were sent to the incorrect patient.

It is our understanding that this firm is now closed. However, Pharmakon Long Term Care Pharmacy, Inc. had committed to FDA in its responses to the Form FDA 483, received June 1, 2016 and June 21, 2016, to correct the deviations in the Form FDA 483. In addition, the deviations identified appeared to be readily correctable.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtained prescriptions for identified individual patients, and FDA believes that the corrective actions can be appropriately overseen by the State if the firm resumes operations. Therefore, FDA is referring this matter to the Indiana State BOP for follow-up to ensure appropriate corrective action is taken.

If this firm decides to resume operations, 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 M. Pawlowski, Compliance Officer, at (313) 393-8217, or by email at tina.pawlowski@fda.hhs.gov.

Sincerely,

Art O. Czabaniuk
District Director
Detroit District Office