U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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February 21, 2018

UPS NEXT DAY

Darren Covington
Executive Director
Indiana State Board of Pharmacy
402 W Washington St, Room W072
Indianapolis, IN 46204-2739

Dear Mr. Covington:

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, PharMerica, LLC located at 6330 E 75th Street Suite 322 Indianapolis, IN 46250-2708 (CSR-Pharmacy and Pharmacy License # 60005275B and 60005275A).

FDA inspected the firm from February 6, 2017, to February 23, 2017. Indiana 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/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm552505.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, 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 investigators reviewed a small sample of records for products compounded by PharMerica, 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. In the response to the Form FDA 483, received on March 15, 2017, the firm advised FDA that it "is committed to ensuring that the operations of the Indianapolis Facility comply with applicable federal and state laws that govern a 503A compounding pharmacy."

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. Examples of deviations observed during our inspection include:

1. Personnel engaged in aseptic processing did not demonstrate adequate aseptic technique. Specifically, personnel had exposed skin inside the ISO 5 aseptic processing area, exposed sterile syringe caps to air of less than ISO 5 quality, rested arms on the surface of the ISO 5 hood during production, and failed to sanitize gloved hands prior to performing work in the ISO 5 hood.
2. Cleaning and disinfecting of the ISO 5 aseptic processing areas were inadequate. For example, the firm failed to use a sporicidal agent in the ISO 5 hoods, and used non-sterile wipes to sanitize the interior of the ISO 5 hood surfaces.

PharMerica, LLC committed to correcting the deviations in its response to the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable. However, it was noted during our review of their supporting documentation that the revised cleaning procedure (EN.003) lacked sufficient detail to ensure consistent and thorough cleaning of the aseptic processing areas.

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 Indiana 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 Tina M. Pawlowski, Ph.D., Compliance Officer, at (313-393-8217) or by email at Tina.Pawlowski@fda.hhs.gov.

Sincerely,

Nicholas F. Lyons -S

Digitally signed by Nicholas F. Lyons -S
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Date: 2018.02.21 10:19:16 -06'00'

Nicholas F. Lyons
Compliance Director
Division of Pharmaceutical Quality Operations III

for
Art O. Czabaniuk
Program Division Director
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CC: Robert Kulak, R.Ph.
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