DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
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August 11, 2015

Steven W. Schierholt, Esq., Executive Director
Ohio State Board of Pharmacy
77 South High Street, Room 1702
Columbus, OH 43215-6126

Dear Mr. Schierholt:

The purpose of this letter is to refer to the Ohio 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 Ohio BOP, Jungle Jim's Pharmacy, located at 5440 Dixie Highway, Fairfield, OH 45014 (Ohio Retail Pharmacy, Category Three [Credential RTP.021513150-03] and Ohio Wholesale/Pharmacy, Category Two [Credential WPHR.011623950-02]).

FDA inspected the firm from January 12, 2015, to January 26, 2015. FDA investigators were accompanied by Ohio state investigators for two days. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at http://www.fda.gov/downloads/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/oraelectronicreadingroom/ucm433014.pdf.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Jungle Jim's 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 dispenses. In the response to the Form FDA 483, received by FDA on February 13, 2015, the firm stated that it is "not supplying compounds/drugs to the doctors as office supply and only entertain[s] patient-specific prescription[s] to be dispensed/ship[ped] only to the patients."

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. The firm failed to demonstrate through appropriate studies that their hoods are able to provide adequate protection of the ISO 5 area in which sterile products are processed. Specifically, the firm did not perform smoke studies under dynamic conditions to verify that there is no obstruction or alteration of laminar air flow that may contaminate the product.

2. The firm failed to verify that the sterilization process used to terminally sterilize their drug products is effective.

In its Form FDA 483 response, Jungle Jim's Pharmacy committed to correct the deviations in the Form FDA 483. In addition, the deviations identified appear 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 obtains prescriptions for identified individual patients, consistent with traditional pharmacy practice, 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 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 Stephen Rabe, Compliance Officer, at 513-679-2700 (extension 2163), or by email at stephen.rabe@fda.hhs.gov.

Sincerely,

for Toniette K. Williams
Acting District Director
U.S. Food and Drug Administration
Cincinnati District Office