



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
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April 15, 2015

UNITED PARCEL SERVICE **Delivery Signature Requested**

Susan Alverson
Executive Secretary
Alabama State Board of Pharmacy
111 Village Street
Birmingham, Alabama 35242

Dear Ms. Alverson:

The purpose of this letter is to refer to the Alabama 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 Alabama BOP, Wellness Pharmacy, Inc., 3401 Independence Drive, Suite 231, Birmingham, Alabama 35209 (pharmacy licenses 110003 and 200001).

FDA inspected the firm from September 22-26 and 29-30, 2014. FDA investigators were accompanied by Alabama State investigators for each day of 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/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAElectronicReadingRoom/UCM425284.pdf>.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Wellness Pharmacy, Inc., and determined, based on this sample, 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 October 22, 2014, the firm advised FDA that it performs compounding only "pursuant to a valid prescription for an individual patient in compliance with the United States Pharmacopoeia (USP) chapters on pharmacy compounding, USP 795 and USP 797, using bulk drug substances that comply with USP or National Formulary (NF) monographs."

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 their ISO 5 is able to provide adequate protection of the area in which products intended or expected to be sterile are processed.
2. The firm failed to demonstrate that all operators that conduct sterile production are capable of performing aseptic processing in a manner that prevents contamination of the sterile drug products.

Wellness Pharmacy committed to FDA in its response to the Form FDA 483, received October 22, 2014, to correct the deviations in the Form FDA 483.¹ In addition, the deviations identified appear to be readily correctible.

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 the corrective actions can be appropriately overseen by the BOP. Therefore, FDA is referring this matter to the Alabama BOP for follow-up to ensure appropriate corrective action is taken. We would like your follow-up to include human and any animal drugs that this pharmacy may produce. 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 Kari L. Batey, Compliance Officer, at 615-366-7808, or by email at kari.batey@fda.hhs.gov.

Sincerely,



Ruth P. Dixon
District Director
New Orleans District Office

¹ Because you are an FDA commissioned official you can request an unredacted copy of the Form FDA 483 and/or the firm's response to the Form FDA 483.