DEPARTMENT OF HEALTH AND HUMAN SERVICES

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3551

February 20, 2014

UNITED PARCEL SERVICE
David C. Young, Pharm.D.
Chairperson
Utah State Board of Pharmacy
160 East 300 South
Salt Lake City, Utah 84111

Dear Dr. Young:

The purpose of this letter is to refer to the Utah 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 of a pharmacy licensed by the Utah State BOP, University Pharmacy, located at 1320 East 200 South, Salt Lake City, Utah 84102.

FDA inspected the firm from February 19, 2013 to February 22, 2013 and on February 26, 2013. FDA's investigators were accompanied by a Utah State BOP inspector for two days of the inspection. Attached is a redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by University 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.

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 did not perform adequate cleaning and disinfection of the work surfaces, supplies and equipment within the aseptic processing areas. The investigators observed:
   - Spills and spatters of amber and white colored residues on multiple sites within the firm's laminar flow hood.
   - Failure to use sporicidal agents in the laminar flow hood to kill any microbial spores that could be present in the ISO 5 area and represent a significant contamination risk.

2. The aseptic practices employed by personnel at the firm were inadequate and increased the risk of microbial contamination of the product. For example, the investigator observed that:

- The aseptic operator's movements in the ISO-5 laminar flow hood were too fast, risking the disruption of the uni-directional airflow that is protecting open containers of sterile drug products from microbial contamination during aseptic operations.
- An aseptic operator returned to the ISO-7 cleanroom and resumed aseptic operations in the ISO-5 laminar flow hood after transporting cleanroom trash to a "dirtier" area of the facility. The aseptic operator did not change gowning components or disinfect gloves before reaching inside of the laminar flow hood.

University Pharmacy committed to correcting some of the deviations in their March 18, 2013 response to the Form FDA 483.[1]

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. In addition, the deviations identified appear to be readily correctable, and the firm has agreed in writing to correct some of the deviations. Therefore, FDA believes that the corrective actions can be appropriately overseen by the State, and is referring this matter to the Utah 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 our public health mission together with our state partners. If you have additional questions, please contact Thomas Berry, Pharm.D., Compliance Officer, at 303-236-3028, or by email at thomas.berry@fda.hhs.gov.

Sincerely,

LaTonya M. Mitchell

LaTonya M. Mitchell
District Director
Denver District Office

[1] See attached response letter dated March 18, 2013 from Richard Rasmuson, R.Ph to the FDA Denver District Office

bcc: DCB KEM /Legal File
DIB/EI File: FEI # 3004146124
TRB Chrono
Work Activity #67670
RF