U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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March 4, 2020

UPS NEXT DAY
SIGNATURE REQUIRED

Larry Hadley
Executive Director
Kentucky State Board of Pharmacy
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort, KY 40601

Dear Mr. Hadley:

The purpose of this letter is to refer to the Kentucky 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 Kentucky BOP, Nutrishare Inc., located at 11020 Plantside Drive, Louisville, KY 40299-6105 (License Number P06292).

FDA inspected the firm from July 16, 2018, to July 26, 2018. The FDA investigator was accompanied by a Kentucky BOP inspector for one day. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/115829/download, 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 investigator reviewed a small sample of records for products compounded by Nutrishare Inc. 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.

Additionally, during the inspection, the FDA investigator observed deviations from sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during the inspection include:

1. Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

2. ISO 5 classified areas were not certified under dynamic conditions.

3. Materials or supplies were not disinfected prior to entering the aseptic processing areas.

4. Disinfecting agents used in the ISO 5 aseptic processing area were not sterile.

5. The firm produced beta-lactam drugs without providing adequate segregation, cleaning of work surfaces, and cleaning of personnel to prevent cross-contamination.

Nutrishare Inc. committed to correcting the deviations and provided documentation in support of those corrective actions in an August 9, 2018, response to the Form FDA 483 and in May 23, 2019, and December 5, 2019, responses to FDA requests for additional information. In addition, the deviations identified appear to be readily correctable.

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 overseen by the State. Therefore, FDA is referring this matter to the Kentucky State BOP for follow up to ensure 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 Brian Garthwaite, Ph.D., Compliance Officer, at 612-758-7132.

Sincerely,

Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III

cc: Gregory M. Killmeier
Operations Manager & Pharmacist in Charge
Nutrishare Inc.
11020 Plantside Drive
Louisville, KY 40299-6105