Inspections, Compliance, Enforcement, and Criminal Investigations

Compliance Actions and Activities
Warning Letters
2014

Clinical Specialties Compounding Pharmacy 6/27/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration

Atlanta District
60 Eighth Street, NE
Atlanta, GA 30309

June 27, 2014

VIA UPS

WARNING LETTER
(14-ATL-09)

Austin E. Gore
Owner and Pharmacist-in-Charge
Clinical Specialties Compounding Pharmacy
318 Baston Road, Suite 103
Augusta, GA 30907

Dear Mr. Gore:

Between March 18, 2013, and April 2, 2013, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Clinical Specialties Compounding Pharmacy, located at 318 Baston Road, Suite 103, in Augusta, Georgia 30907. FDA inspected your firm after receiving information about five patients diagnosed with bacterial endophthalmitis infections, four of whom were treated at a clinical facility located in Georgia and the fifth treated at a facility in Indiana. All five cases were associated with a total of two lots of Avastin (bevacizumab) repackaged by your firm. On March 15, 2013, your firm voluntarily recalled all Avastin unit dose syringes due to the potential of serious eye infections. On March 20, 2013, your firm expanded the recall to include all lots of products that were intended or expected to be sterile and produced and distributed by your firm since October 19, 2012, due to a lack of sterility assurance.

A. Adulteration Charges

Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 351(a)(2)(A)], a drug is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Numerous subvisible microorganisms and other contaminants are ubiquitous in an ordinary environment.

A firm producing sterile drugs must take certain steps in order to ensure removal of contaminants through various controls that focus on safeguarding drug sterility by assuring the quality of the processing environment (e.g., surfaces, personnel, air). Otherwise, drugs that are intended or expected to be sterile may become contaminated during preparation and, when administered to a patient, may result in infections and/or pyrogenic responses that pose a life-threatening health risk to a patient. Failure to take these steps when producing drugs that are intended or expected to be to be sterile causes the drug to be prepared, packed, or held under insanitary conditions.

FDA investigators observed that your drug products that were intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing these products to be adulterated under section 501(a)(2)(A) of the FDCA [21 U.S.C. § 351(a)(2)(A)]. During FDA's inspection of your firm, the investigators observed poor aseptic practices on the part of your firm's personnel. For example, your firm did not use any sporicidal agent as part of the disinfection program for the clean room and the ISO-5 area. Furthermore, your firm did not sanitize equipment or supplies before placement into the ISO-5 area. Failure to adequately clean and disinfect equipment and supplies

exposes products being aseptically manipulated in the ISO-5 area to a potential source of contamination. The introduction or delivery for introduction into interstate commerce of any adulterated drug is a prohibited act under section 301(a) of the FDCA [21 U.S.C. § 331(a)]. It is also a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce of the components used to make the drug and results in the drug being adulterated.

B. Corrective Actions

In your response to the FDA-483dated April 16, 2013, you indicated that you are permanently discontinuing the production of sterile drug products at your facility effective March 8, 2013, and that you do not intend to prepare or sell any sterile products in the future. You also committed to implementing corrective and preventative actions based on relevant State and Federal guidelines.

C. Conclusion

Please note that the violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. You are responsible for investigating and determining the causes of the insanitary conditions identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

If you decide to resume sterile operations, you should take prompt action to correct the insanitary conditions cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing if you have taken any specific steps to address the insanitary conditions at your firm, or you may inform us that you do not intend to resume production of sterile drugs. If you intend to resume production of sterile drugs in the future, please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. In addition to taking appropriate corrective actions, you should notify this office prior to resuming production of any sterile drugs in the future. Your written notification should be addressed to:

Marie Mathews, Compliance Officer
FDA Atlanta District Office
U.S. Food and Drug Administration
60 8th Street, N.E.
Atlanta, GA 30309

If you have questions regarding any issues in this letter, please contact our office at 404-253-1279.

Sincerely,
/S/
Ingrid S. Zambrana, Director
Atlanta District

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