Essential Pharmacy Compounding 3/10/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Kansas District Office
8050 Marshall Drive, Suite 205
Lenexa, KS 66214
Telephone: (913) 495-5100
Fax: (913) 495-5115

WARNING LETTER

March 10, 2016

Justin M. Kholl, Vice President
Essential Pharmacy Compounding
620 N. 114th Street
Omaha, NE 68154-1571

Dear Mr. Kholl:

From May 12, 2015, to May 22, 2015, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Essential Pharmacy Compounding, located at 620 N. 114th Street, Omaha, NE 68154-1571.

During the inspection, the FDA investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, our investigators noted that your firm did not establish an adequate contact time for your sporicidal agent used to disinfect your aseptic processing areas. Furthermore, your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 areas in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk.

FDA issued a Form FDA 483 to your firm on May 22, 2015. FDA acknowledges your firm's responses to the Form FDA 483, dated June 11, 2015 and October 22, 2015.

Based on this inspection, it appears that you are producing drugs that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigators observed that your drug products 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 your drug products to be

adulterated under section 501(a)(2)(A) of the FDCA [21 U.S.C. § 351(a)(2)(A)]. For example, the FDA investigators noted that your firm did not establish an adequate contact time for your sporicidal agent used to disinfect your aseptic processing areas. Furthermore, your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 areas in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk.

B. Corrective Actions

We acknowledge your responses to the Form FDA 483 inspectional observations, dated June 11, 2015 and October 22, 2015. Although several of your proposed corrective actions appear adequate, others are deficient. For example, in your response to our observation regarding the contact dwell time for **(b)(4)**, your firm amended its cleaning and disinfection policy to include a **(b)(4)** requiring a **(b)(4)** contact dwell time. However, the manufacturer recommends that "**(b)(4)**" for use as a sporicide, and you did not provide documentation to justify this reduced dwell time.

In addition, your response includes a room certification report dated **(b)(4)**, which noted that smoke studies for **(b)(4)** of your hoods were documented with a "pass" result. However, you did not provide documentation (e.g., description of the conditions at the time of the smoke studies, videos of the smoke studies) to show that these studies were performed under dynamic conditions. Furthermore, we noted that the equipment used to measure and verity pressure differentials in your room certification report dated **(b)(4)** was past due for required calibration.

FDA strongly recommends that your management immediately undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise could be useful in conducting this comprehensive evaluation.

C. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. lt is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations 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 of the specific steps that you have taken to correct the violations. 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. If you cannot complete the corrective actions within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please address your reply to:

Danial Hutchison, Compliance Officer
FDA Kansas City District Office
U.S. Food and Drug Administration

8050 Marshal Drive, Suite 250
Lenexa, KS 66214

If you have questions regarding any issues in this letter, please contact Mr. Hutchison via email at Daniai.Hutchison@fda.hhs.gov or by phone at (913) 495-5154.

Sincerely,
/S/
Cheryl A Bigham
District Director
Kansas City District

Firm Response Letter

- Essential Pharmacy Compounding Response Letter 3/24/16