Bedford Pharmacy 5/18/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District Office
One Montvale Avenue, 4th floor
Stoneham, MA 02180
Phone 781.587.7500
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WARNING LETTER
CMS# 486159

Via UPS Next Day Air
Delivery confirmation requested

May 18, 2016

Mr. Ronald L. Petrin, Pharmacist
Bedford Pharmacy, Inc.
209 Route 101
Bedford, NH 03110

Dear Mr. Petrin:

From August 10, 2015, to August 28, 2015, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Bedford Pharmacy, Inc. located at 209 Route 101, Bedford, NH 03110.

During the inspection, the 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's **(b)(4)**, where aseptic processing occurs, is located in an unclassified room and is turned off when not in use. Moreover, your firm exposed the **(b)(4)** to air in an unclassified room during cleaning, which is significant as your **(b)(4)** is not self-sterilizing. In addition, your firm failed to use a sporicidal agent and sterile wipes as part of your disinfection program for the aseptic processing area. Furthermore, your firm failed to demonstrate through appropriate studies that your aseptic processing area is able to provide adequate protection of the ISO 5 area in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk.

A Form FDA 483 was issued to your firm on August 28, 2015. FDA acknowledges your September 15, 2015, response to the Form FDA 483 and your action on September 22, 2015, to voluntarily recall all sterile drug products within expiry, and to temporarily cease compounding sterile drug products. Based on this inspection, it appears that you have produced drugs that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

FDA investigators observed that drug products that are 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, our investigators noted that your firm's **(b)(4)**, where aseptic processing occurs, is located in an unclassified room and is turned off when not in use. Moreover, your firm exposed the **(b)(4)** to air in an unclassified room during cleaning, which is significant as your **(b)(4)** is not self-sterilizing. In addition, your firm failed to use a sporicidal agent and sterile wipes as part of your disinfection program for the aseptic processing area. Furthermore, your firm failed to demonstrate through appropriate studies that your aseptic processing area is able to provide adequate protection of the ISO 5 area in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk.

Under section 301(k) of the FDCA [21 U.S.C. §331(k)], it is a prohibited act 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 and results in the drug being adulterated.

B. Corrective Actions

We acknowledge your action taken on September 22 2015, to voluntarily recall all sterile drug products within expiry, and to temporarily suspend the production of sterile products. We further acknowledge your September 15, 2015, response to the Form FDA 483 that was issued to your firm at the conclusion of the inspection. Although several of your proposed corrective actions appear adequate, others are deficient. To address the location of your **(b)(4)** in an unclassified area, you provided a statement from the manufacturer, which indicates that the current location is an acceptable environment. However, we remain concerned that your current location does not mitigate the risk associated with the ingress of microbial contamination concurrent with the influx of unclassified air during routine cleaning and maintenance. Furthermore, your response did not address the impact of the **(b)(4)** being turned off when not in use.

Your response lacked sufficient evidence that the proposed cleaning and disinfecting procedures are capable of producing environmental conditions appropriate for aseptic processing.

We acknowledge your firm's commitment to conduct smoke studies under dynamic conditions. However, you did not provide a detailed description of the conditions in

which the studies will be conducted for our review. When completed, we recommend that you provide a detailed description of the conditions at the time of the smoke studies or a video copy of the smoke studies.

If you decide to resume production of sterile drugs, 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. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

If you decide to resume sterile operations, 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. FDA may re-inspect your facility to verify corrective actions have been completed.

Within fifteen working days of receipt of this letter, please notify this office in writing if you have taken any specific steps to correct violations, 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: Maya M. Davis, FDA New England District Office, U.S. Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

If you have questions regarding any issues in this letter, please contact Ms. Davis at 860-240-4289 ex. 25.

Sincerely,
/S/
Joseph Matrisciano, Jr.
District Director
New England District