Kalman Health & Wellness, Inc. dba Essential Wellness Pharma 7/22/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Chicago District Office
Central Region
550 W. Jackson Blvd., 15th Floor
Chicago, IL 60661
Telephone: (312) 353-5863
FAX: (312) 596-4187

July 22, 2016

WARNING LETTER

CHI-8-16

VIA UPS NEXT DAY
SIGNATURE REQUIRED

William J. Kalman, President and Co-Owner
Kalman Health & Wellness, Inc., dba Essential Wellness Pharmacy 2
4625 N. University St.
Peoria, IL 61614-5828

Dear Mr. Kalman:

From June 2, 2015, to July 21, 2015, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Kalman Health & Wellness, Inc., dba Essential Wellness Pharmacy 2, located at 4625 N. University St., Peoria, IL 61614-5828.

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 the HEPA filters and your laminar flow hood within the aseptic processing area **(b)(4)**. This is of great significance because, **(b)(4),** your firm does not conduct adequate disinfection prior to conducting aseptic production. Our investigators noted that your firm did not use a sporicidal agent, sterile **(b)(4)**, and

used non-sterile disinfectants as part of your disinfection program for the aseptic processing area. In addition, our investigators observed brown stains on the HEPA filter in your laminar airflow hood where sterile drug production occurs. Furthermore, your firm failed to demonstrate through appropriate studies that your hood is able to provide adequate protection of the ISO 5 area in which sterile products are processed. Therefore, your products may have been produced in an environment that poses a significant contamination risk.

FDA investigators collected environmental samples of multiple locations in your facility, including the aseptic processing area and **(b)(4)** used to disinfect the aseptic work surface. Testing results of the samples identified microbial contamination, including spore-forming bacteria.

FDA issued a Form FDA 483 to your firm on July 21, 2015. FDA acknowledges receipt of your firm's response to the Form FDA 483 dated August 26, 2015. We also acknowledge your commitment on August 19, 2015 to cease production and distribution of sterile products until adequate corrective actions have been taken, and to initiate a voluntary recall of all aseptic products by August 27, 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

FDA investigators observed that drug products in your facility 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 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:

1. Our investigators noted that the HEPA filters and your laminar flow hood within the aseptic processing area were **(b)(4)** when not in use. This is of great significance because, **(b)(4)**, your firm does not conduct adequate disinfection prior to conducting aseptic production.

2. Our investigators noted that your firm did not use a sporicidal agent, sterile **(b)(4)**, and used non-sterile disinfectants as part of your disinfection program for the aseptic processing area. In addition, your firm conducted environmental monitoring of surfaces **(b)(4)**, which could potentially bias the results.

3. Our investigators observed brown stains on the HEPA filter in your laminar airflow hood where sterile drug production occurs.

4. Your firm failed to demonstrate through appropriate studies that your hood is able to provide adequate protection of the ISO 5 area in which sterile products are processed. Therefore, your products may have been produced in an environment that poses a significant contamination risk.

FDA investigators collected environmental samples of multiple locations in your facility, including the aseptic processing area and **(b)(4)** used to disinfect the aseptic work surface. Testing results of the samples identified microbial contamination, including spore-forming bacteria.

Under section 301(a) of the FDCA, the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA 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

FDA acknowledges your commitment on August 19, 2015, to cease production and distribution of sterile products until adequate corrective actions have been taken, and to initiate a voluntary recall of all sterile products within expiry by August 27, 2015. FDA further acknowledges receipt of your response to the Form FDA 483, dated August 26, 2015, in which you state that your firm **(b)(4)**

If you decide to resume production of sterile drugs, before resuming such production, FDA strongly recommends that your management ensure that you complete 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 and your third party consultant should have relevant aseptic processing expertise.

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.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct 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 the corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed. In addition to taking appropriate corrective actions, you should notify this office 15 working days prior to resuming production of any sterile drugs in the future. Your written notification should be addressed to:

Carrie Ann Plucinski, Compliance Officer
FDA Chicago District Office
550 W. Jackson Blvd., 15th floor
Chicago, IL 60661

Refer to the Unique Identification Number (CMS # 487023) when replying. If you have questions regarding the content of this letter, please contact Ms. Plucinski via email at carrie.plucinski@fda.hhs.gov or by phone at (312) 596-4224.

Sincerely,
/S/
William R. Weissinger
District Director