American Pharmacy of Illinois, Inc. dba Alwan's Pharmacy 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-9-16

VIA UPS NEXT DAY
SIGNATURE REQUIRED

Michael Minesinger, President
American Pharmacy of Illinois, Inc. dba Alwan Pharmacy and Compounding Center
311 N. Western Avenue
Peoria, IL 61604-5638

Dear Mr. Minesinger:

From September 9, 2015, to October 28, 2015, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your facility, American Pharmacy of Illinois, Inc. dba Alwan Pharmacy and Compounding Center, located at 311 N. Western Avenue, Peoria, IL 61604-5638.

During the inspection, the FDA investigator observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, our investigator noted that your firm failed to use sterile **(b)(4)** and did not establish an adequate contact time for the 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 have been produced in an environment that poses a significant contamination risk.

FDA issued a Form FDA 483 and an amended Form FDA 483 to your firm on October 28, 2015, and November 17, 2015, respectively. FDA acknowledges receipt of your firm's response to the amended Form FDA 483, dated November 19, 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 investigator 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, our investigator noted that your firm failed to use sterile **(b)(4)** and did not establish an adequate contact time for the 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 have been produced in an environment that poses a significant contamination risk.

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

We acknowledge your response to the Form FDA 483 inspectional observations, dated November 19, 2015. Although, several of your proposed corrective actions appear adequate, your response is deficient in that it does not include supporting documentation for us to fully evaluate your response. For example, your firm provided an executive summary prepared by your service contract provider that did not include a description of the conditions under which the smoke studies were conducted or a video recording of such studies.

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 processing 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.

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. Your written notification should be addressed to:

Carrie Ann Plucinski, Compliance Officer
Chicago District Office
550 W. Jackson Blvd., Suite 1500
Chicago, IL 60661

Refer to the Unique Identification Number (CMS # 493734) 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