Central Illinois Compounding, Inc. dba Preckshot Professional Pharmacy 9/2/16

Department of Health and Human Services

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

September 2, 2016
WARNING LETTER
CHI-13-16

VIA UPS NEXT DAY
SIGNATURE REQUIRED

Wade A. Siefert, Co-owner
Jennifer A. Siefert, Co-owner
Central Illinois Compounding, Inc.
dba Preckshot Professional Pharmacy
5832 North Knoxville Ave., Suite E
Peoria, IL 61614

Dear Mr. Wade Siefert and Ms. Jennifer Siefert:

From April 15, 2015 to May 14, 2015, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your facility, Central Illinois Compounding, Inc., dba Preckshot Professional Pharmacy, located at 4450 N. Prospect Rd. #7, Peoria Heights, Illinois 61616-6578. FDA notes that since the inspection, your firm has relocated to 5832 N. Knoxville Avenue, Suite E, Peoria, IL 61614.

During the inspection, the investigator observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, the investigator found that your firm failed to use a sporicidal agent in the compounding areas. In addition, your firm failed to demonstrate through appropriate studies that your hoods are 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.

FDA issued a Form FDA 483 to your firm on May 14, 2015. FDA acknowledges receipt of your firm’s response to the Form FDA 483 dated June 12, 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 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 within the meaning of section 501(a)(2)(A) of the FDCA [21 U.S.C. § 351(a)(2)(A)]. For example, the investigator observed that:

1. Your operator passed **(b)(6)** gloved hands over open drug containers, closures, and components while producing sterile drug product.

2. Your firm's system for cleaning and disinfecting the processing areas and equipment to produce aseptic conditions are deficient. Specifically, your firm failed to use a sporicidal disinfectant in compounding areas.

3. Your firm's procedures designed to demonstrate that your ISO 5 areas are able to provide adequate protection to prevent microbiological contamination of drug products purporting to be sterile are not adequate. Specifically, smoke studies are not performed under dynamic conditions.

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 and results in the drug being adulterated.

B. Corrective Actions

In your response to the Form FDA 483 inspectional observations, dated June 12, 2015, you described certain corrective actions you took to address the observations. Although several of your proposed corrective actions that address the identified insanitary conditions appear to be adequate, certain corrective actions appear to be deficient. For example, your response states that dynamic smoke studies were performed in the ISO-5 areas **(b)(4)**. However, the certification report for the ISO 5 areas that FDA collected during the inspection does not state the smoke studies were performed under dynamic conditions. In addition, the report indicated neither what activities were simulated nor the number of personnel present in the cleanroom during the study. Furthermore, you have not submitted a more recent report, showing that your firm has performed smoke studies under dynamic conditions.

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.

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 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 frame within which corrections will be completed.

Your written notification should be addressed to:

Nicholas Lyons, Compliance Director
FDA Chicago District Office
550 W. Jackson Blvd., 15th floor
Chicago, IL 60661

Refer to the Unique Identification Number (CMS # 487024) when replying. If you have questions regarding the content of this letter, please contact Mr. Lyons via email at Nicholas.lyons@fda.hhs.gov or by phone at (312) 596-4220.

Sincerely,
/S/
William R. Weissinger
District Director