

# Coram Healthcare Corp. of Indiana 8/11/15



Department of Health and Human Services

Public Health Service  
Food and Drug  
Administration  
Detroit District  
300 River Place  
Suite 5900  
Detroit, MI 48207  
Telephone: 313-393-8100  
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## Warning Letter 2015-DET-18

### VIA UPS

August 11, 2015

Wanda Rogers, Pharmacy Director  
Coram Healthcare Corporation of Indiana  
dba Coram CVS/Specialty Infusion Services  
Crown Point Branch  
1290 Arrowhead Court, Suite A  
Crown Point, IN 46307-7766

Dear Ms. Rogers:

From December 1, 2014, to December 16, 2014, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility located at 1290 Arrowhead Court, Suite A, Crown Point, IN 46307-7766.

During the inspection, the investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, the operator's gloves were not always appropriately sanitized with sterile **(b)(4)** before the operator's gloved hands were placed under the ISO 5 laminar flow hood (LFHT). The investigator also found that 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 drug products are produced. 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 December 16, 2014. 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 that are intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health, causing them to be adulterated under section 501(a)(2)(A) of the FDCA [21 U.S.C. §351(a)(2)(A)]. For example:

1. The aseptic practices employed by personnel at your firm were observed to be inadequate and increased the risk of microbial contamination of the product. Specifically, the investigators observed your operator rest gloved hands on the workbench surface of the ISO 5 laminar flow hood (LFH), and the operator's gloves were not always appropriately sanitized with sterile **(b)(4)** before the operator's gloved hands were placed under the ISO 5 LFH.
2. The investigators noted that your firm did not perform adequate cleaning and disinfection of the work surfaces, supplies, and equipment within the aseptic processing areas. For instance, beta-lactam products are aseptically processed under the LFH that is also used for non-beta lactam products. In addition, your firm's beta lactam controls do not include data to support that the spill procedure clean up, which includes use of sterile **(b)(4)** and non-sterile, disposable lint-free wipes to wipe surfaces in the ISO 5 LFH is effective in mitigating potential beta lactam residues if present.
3. The investigators found that your firm failed to demonstrate through appropriate studies that the ISO 5 LFH is able to provide adequate protection of the area in which products intended or expected to be sterile are processed. For example, smoke studies under dynamic conditions were not performed to evaluate unidirectional airflow patterns over products in the ISO 5.

Under section 301(k) of the FDCA, 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**

In your response to the Form FDA 483 inspectional observations, dated January 23, 2015, you referenced your firm's purported compliance with United States Pharmacopeia (USP) – National Formulary (NF) General Chapter <797> Pharmaceutical Compounding –Sterile Preparations. You state that your firm meets the requirements for exemption from section 501(a)(2)(B) of the FDCA [21 U.S.C. § 351(a)(2)(B)] provided by section 503A. However, compounded drug products that qualify for the exemptions in section 503A remain subject to all other applicable provisions of the FDCA, including the requirement that the drug products are not prepared, packed, or held under insanitary conditions (section 501(a)(2)(A) of the FDCA [21 U.S.C. § 351(a)(2)(A)]). Your firm's response to the deficiencies described above involving insanitary conditions cannot be evaluated because you failed to

provide documentation or sufficient detail of your corrective actions to determine their adequacy.

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 and 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. Your written notification should be addressed to:

Tina Pawlowski, Ph.D., Compliance Officer  
FDA Detroit District Office  
U.S. Food and Drug Administration  
300 River Place, Suite 5900  
Detroit, MI 48207

If you have questions regarding any issues in this letter, please contact Dr. Pawlowski via email at [tina.pawlowski@fda.hhs.gov](mailto:tina.pawlowski@fda.hhs.gov) or by phone at (313) 393-8217.

Sincerely,  
/S/  
Art Czabaniuk  
District Director  
Detroit District