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
FAX: 313-393-8139

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 undersection 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 or by phone at (313) 393-8217.

Sincerely,
/S/
Art Czabaniuk
District Director
Detroit District

More in 2015

Page Last Updated: 09/15/2015
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)