DATE: 3/25/2022

Case #: 627763

VIA EMAIL CONFIRMED DELIVERY

Thomas J. Wilverding, President
Central Admixture Pharmacy Services, Inc.
1433 Sams Avenue, Units A and C
Harahan, LA, 70123- 5525

Dear Mr. Wilverding:

From May 3, 2021, to May 24, 2021, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Central Admixture Pharmacy Services, Inc., located at 1433 Sams Avenue, Units A and C, Harahan, LA, 70123. During the inspection, the investigator noted deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on May 24, 2021. FDA acknowledges receipt of your facility's response, dated June 14, 2021. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or

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rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed that:

1. Personnel failed to disinfect or change gloves during aseptic processing when moving from an ISO 7 environment into an ISO 5 environment. Specifically, Personnel did not sanitize their gloves or adequately sanitize their gloves each time they moved from ISO 7 to ISO 5 conditions during aseptic processing.

2. Equipment, materials, and/or supplies were not always disinfected prior to entering critical aseptic processing areas from lower classified areas. For example, (b) (4) were not sprayed or wiped with sterile (b) (4) when moving from ISO 7 to ISO 5 prior to use of the port for final ingredient addition. And (b) (4) syringes were not adequately sanitized when being moved from ISO 7 to ISO 5 conditions. Improper disinfection of materials when moving from areas of lower to higher classification (i.e., ISO 7 to ISO 5) poses contamination risk for all impacted drug products.

3. Your firm failed to perform adequate product evaluation and take appropriate corrective action after microbial contamination was recovered within the ISO 5 aseptic processing area and from personnel fingertips.

4. Your firm failed to establish an adequate contact time for your sporicidal agent used to disinfect your ISO 5 aseptic processing area and ISO 7 area. Specifically, your (b) (4) solution was not allowed to contact cleanroom equipment surfaces for the minimum dwell time indicated on the label for disinfection and as required in your respective procedures for sporicidal effectiveness during (b) (4) cleaning.

5. Production equipment located in an ISO 7 environment, including ISO 5 Laminar Air Flow Hoods, were observed to have difficult to clean surfaces.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act.

C. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding your response related to the insanitary conditions, some of your corrective actions appear adequate; however, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. You state you retrained personnel on aseptic technique, cleaning technique, and disinfection of materials entering critical processing areas from lower classified

areas. However, your response did not include if you evaluated whether there was the potential for product impact from the observed poor aseptic technique. Nor did your response provide a retrospective review of training records, cleaning and dwell time logs, or include results of media fill tests along with measures to ensure additional personnel oversight.

2. You provided your procedures on your firm's process when finding microbial contamination. However, your response did not provide a rationale for your practice of resampling to confirm alert level results, no action taken when growth is detected from (b) (4) sampling, and your practice of not identifying microorganisms recovered via surface and (b) (4) sampling, or whether cleaning was and will be conducted in response to the detection of contamination.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

D. 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 any violations 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.

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to address any violations. Please include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. If you believe that your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time within which you will do so.

Your written notification should refer to case # 627763 .

Please electronically submit your reply, on company letterhead, to Mark W. Rivero, Compliance Officer, at ORAPHARM2_RESPONSES@fda.hhs.gov. In addition, please

submit a signed copy of your response to mark.rivero@fda.hhs.gov and ORAPHARM2ActingDCB@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact Mr. Rivero via phone at (504) 846-6103 or email at the above email address.

Sincerely,

Jose R. Lopez Martinez -S

Digitally signed by Jose R. Lopez Martinez -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000379053, cn=Jose R. Lopez Martinez -S
Date: 2022.03.25 09:25:28 -04'00'

Jose R. Lopez
Acting Director, Compliance Branch
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