U.S. FOOD & DRUG ADMINISTRATION

November 3, 2022

Mr. Joseph Fontenot, Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700

Ref: CMS Case 627763, FEI 3005292119

State Referral Letter

Dear Mr. Fontenot:

The purpose of this letter is to refer to you, the Louisiana Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy you licensed, Central Admixture Pharmacy Services, Inc., located at 1433 Sams Avenue, Units A & C, Harahan, LA 70123.

FDA inspected the firm from 5/3/2021 to 5/24/2021. FDA investigators were accompanied by your state investigators for part of the inspection.

A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/152334/download, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for drug products compounded by Central Admixture Pharmacy Services, Inc., and FDA does not intend to take further actions at this time related to conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

During the inspection, the FDA investigator observed deviations from appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk.

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Central Admixture Pharmacy Services, Inc., committed to FDA in its response to the Form FDA 483 on 6/14/2021 to correct the deviations in the Form FDA 483. An Untitled Letter was issued on 3/25/2022 and can be found at https://www.fda.gov/media/162406/download. Examples of corrective actions which could not be evaluated for adequacy due to insufficient information or supporting documentation include:

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.

Central Admixture Pharmacy Services, Inc., committed to FDA in its response to the Untitled Letter on 4/26/2022 and 5/4/2022 to correct outstanding deviations in the Untitled Letter and provided documentation in support of those corrective actions.

After review of the records, FDA does not intend to take further action at this time with regard to the findings of this inspection. FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to you for follow up to ensure appropriate corrective action has been taken. We believe you, the State, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce. Please notify us if you become aware of any adverse events or product quality concerns associated with drug products made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Rebecca Asente, Compliance Officer, at (504) 846-6104 or rebecca.asente@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

Jose R. Lopez Martinez -S

Digitally signed by Jose R. Lopez Martinez -S
Date: 2022.11.03 20:28:50 -04'00'

Jose R. Lopez
Acting Director, Compliance Branch
Office of Pharmaceutical Quality Operations
Division II

Cc: Thomas J. Wilverding, President
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Harahan, LA, 70123- 5525