U.S. FOOD & DRUG ADMINISTRATION

August 13, 2024

Kelly Rogers, Chief
Bureau of Health Care Practitioner Regulation
Florida Board of Pharmacy
4052 Bald Cyress Way, Bin C-04
Tallahassee, FL 32399-3254
MQA.Pharmacy@flhealth.gov

Ref: CMS WA #561409, FEI #3009339218

State Referral Letter

Dear Kelly Rogers:

The purpose of this letter is to refer to you, the Florida 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, Jubilant DraxImage Radiopharmacies, Inc., dba Jubilant Radiopharma, located at 4205 Vineland Road, Suite L13, Orlando, FL 32811-6601.

FDA inspected the firm from March 5, 2024, to March 13, 2024. FDA investigators were accompanied by your State investigator for part of the inspection.

A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/178630/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 investigators observed deviations from appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. Personnel were observed performing aseptic processing outside of an ISO 5 area.

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Office of Regulatory Affairs
Office of Pharmaceutical Quality Operations, Division II
1201 Main Street, Suite 7200
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2. Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

3. Personnel used non-sterile disinfectant(s), and wipes within the ISO 5 aseptic processing area.

4. Media fills were not performed under the most challenging or stressful conditions. Therefore, there was a lack of assurance the firm could aseptically produce drug products.

Jubilant DraxImage Radiopharmacies, Inc., dba Jubilant Radiopharma, committed to FDA in its responses to the Form FDA 483, dated April 2, 2024, and updated June 3, 2024, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

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,

Ronda R. Loyd-jones -S

Digitally signed by Ronda R. Loyd-jones -S
Date: 2024.08.12 20:40:36 -07'00'

Ronda R. Loyd-Jones
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

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