DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	3/5/2024-3/13/2024* FEI NUMBER 3009339218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Larry E. Jones Jr., Pharmacy Manager

FIRM NAME	STREET ADDRESS
Jubilant DraxImage Radiopharmacies Inc. dba Jubilant Radiopharma	4205 Vineland Rd Ste L13
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32811-6601	Nuclear Pharmacy

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically, on 03/06/24, during the production of Gozetotide (Illucix) Cold Kit Lot# K-20240306-069 your firm's Pharmacy Manager was observed performing the following aseptic connections in the ISO-7 aseptic processing area: connecting the (b) (4) sterile (b) (4) to the Gallium Generator and connecting the Sterile (b) (4) to the Gallium Generator. The following prescriptions were drawn from the cold kit and dispensed: RX (b) (6), (b) (7)(C) (13.94 mCi) and RX (b) (6), (b) (7)(C) (25.49 mCi).

OBSERVATION 2

Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

Specifically, on 03/06/24, during the production of Gozetotide (Illucix) Cold Kit Lot# K-20240306-069 your firm's Pharmacy Manager was observed blocking first pass air in the ISO-5 (b) (4) flow hood. The following prescriptions were drawn from the cold kit and dispensed: RX (b) (6), (b) (7)(C) (13.94 mCi) and RX (b) (6), (b) (7)(C) (25.49 mCi).

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica P Mcalister, Investigator Jared P Stevens, Investigator	X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 03-13-2024 14:13:28	3/13/2024

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Use of non-sterile disinfecting agents and cleaning pads in the ISO 5 area.

Specifically, your firm utilizes the following non-sterile cleaning agents (b) (4) (b) (4) and non-sterile (b) (4) within your (b) (4) ISO 5 (b) (4) flow hoods and (b) (4) ISO 5 BSCs.

OBSERVATION 4
Smoke studies were inadequately performed under dynamic conditions.

Specifically, on 03/16/24, inadequate smoke studies were observed within your firm's ISO 5 (b) (4) flow hood (video-SN:155019, 3:15). Turbulent and non-unidirectional airflow was observed during the operations. Ancillary supplies such as syringe containers and a labeling printer were observed blocking the grates and return vent within the hood allowing for air to recirculate.

OBSERVATION 5
Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically, during the current FDA inspection, your firm determined that your media fill is not reflective of Gozetotide (Illucix) which is the most challenging drug product to produce because of the number of manipulations and poses the highest risk to product sterility due to the transfer from the ISO-5 (b) (4) flow hood to the Gallium Generator (requires aseptic connections) that is housed within the ISO 7 aseptic processing area.

OBSERVATION 6
Inadequate routine environmental monitoring in the ISO 5 area and classified areas.

Specifically, your firm was unable to determine that viable surface sampling of the ISO-5 environment (e.g., ISO-5 LAFHs and BSCs) occurs prior to cleaning operations.

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*DATES OF INSPECTION

3/05/2024(Tue), 3/06/2024(Wed), 3/07/2024(Thu), 3/08/2024(Fri), 3/11/2024(Mon), 3/13/2024(Wed)

X Jared P Stevens
Investigator
Signed By: Jared P. Stevens -S
Date Signed: 03-13-2024 14:13:57

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jessica P Mcalister, Investigator Jared P Stevens, Investigator X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 03-13-2024 14:13:28	3/13/2024

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."