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	6/8/2026-6/12/2026
	FEI NUMBER 3032541011

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Leighton Gray, PharmD, Facility Manager

FIRM NAME	STREET ADDRESS
SOFIE Co dba Sofie	14324 - 28 Commerce Way
CITY, STATE, ZIP CODE, COUNTRY Miami Lakes, FL 33016-1501	TYPE ESTABLISHMENT INSPECTED PET Drug Manufacturer

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 I OBSERVED:
These observations were identified during a pre-approval inspection conducted in support of the (b)(4) Injection; (b)(4) Injection USP; and (b)(4) Injection (b)(4) (b)(4)) — (b)(4) PET drug products.

OBSERVATION 1

You did not conduct identity testing on each lot of component that yields an active ingredient and inactive ingredient in a PET drug product for which you did not conduct finished product testing to ensure that the correct components were used.

Specifically, suppliers of the precursor materials listed below, which are used in the manufacture of sterile injectable PET drug products (solution for injection/infusion), have been qualified without establishing the reliability of the suppliers' Certificates of Analysis (CoAs) through appropriate confirmatory testing. Furthermore, no process or program has been established, nor has complete testing been performed at appropriate intervals, to assess and verify the continued reliability of the suppliers' Certificates of Analysis.

Below are examples of Precursors received and their associated finished product lot:

(b)(4) **Product Name**	**Precursor**	**Lot #**

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EMPLOYEE(S) SIGNATURE
Adetutu M Gidado, Investigator

X Adetutu M Gidado Investigator Signed By: 2001865804 Date Signed: 06-12-2026 14:41:29

DATE ISSUED
6/12/2026

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(b)(4)

OBSERVATION 2

You lack personnel with the necessary background and training to perform their assigned functions.

Specifically, personnel performing aseptic processing operations did not consistently follow established procedures designed to prevent contamination of sterile PET drug products. During the facility walkthrough and review of smoke study video recordings, the following practices were observed:

a. Operators did not perform adequate hand sanitization during aseptic operations.
b. Operators were observed touching the inner sleeve/cuff of a sterile glove prior to donning it with an already gloved sterile hand, thereby compromising glove integrity.
c. Operators' sterile gowns were observed to open during operations, exposing underlying street clothing and creating a potential contamination risk.
d. Items were removed from sterile bags by dumping the contents directly onto the work surface within

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the (b) (4) Hot Cell (b) (4)), rather than using appropriate aseptic technique.

e. Trash was allowed to accumulate within the ISO 5 Laminar Airflow Hood (LAFH) during aseptic operations.

f. Exposed skin on the forehead, nose, and around the eyes of operators was observed in the ISO 7 classified clean room, contrary to gowning requirements.

g. Operators did not maintain the ISO 5 work area in a clutter-free condition or arrange materials to permit aseptic manipulations from the cleanest area or surface to the least clean area or surface.

h. An operator was observed extending their upper body into the ISO 5 (b) (4) Hot Cell (b) (4) while performing cleaning activities, thereby disrupting first-air protection of the critical work area. During the activity, the operator's sterile gown was observed to be open, exposing underlying street clothing and increasing the potential for contamination of the ISO 5 environment.

OBSERVATION 3

You did not establish and follow written quality assurance procedures.

Specifically:

a. Procedures governing review of analytical data used for batch release do not require review of electronic raw data or audit trails generated by computerized analytical systems. Consequently, there is no documented assessment to determine whether data have been modified, deleted, reprocessed, or otherwise altered.

b. Written procedures for disinfection of aseptic processing areas were not adequately implemented. Operators were observed using a single sterile wipe on multiple surfaces before disposal.

c. (b) (4) used for (b)(4) testing are retained and reused within the (b) (4) Hot Cell (b) (4) for up to (b) (4). There is no documented scientific justification to support the assigned (b) (4) hold time or expiration period for these (b) (4).

d. Smoke studies used to evaluate airflow patterns in ISO 5 and ISO 7 aseptic processing areas did not demonstrate that unidirectional airflow adequately protects exposed sterile materials and critical operations. Smoke was observed moving upward toward the HEPA filter and away from critical processing areas during simulated operations.

e. Smoke studies were conducted using smoke generated from (b) (4) with an undetermined density. The firm has not demonstrated that the smoke generation system produces neutrally buoyant smoke suitable for accurately visualizing airflow patterns. Therefore, the adequacy of the smoke studies to demonstrate unidirectional airflow and protection of critical aseptic processing operations has not been established.

f. Environmental monitoring (EM) of the ISO 7 classified area is not adequately performed. (b)(4) worktables, benches, and (b)(4) used for staging and handling materials within the ISO 7 area are not included in the environmental monitoring program, leaving critical surfaces unmonitored.

OBSERVATION 4

Your firm lacks adequate production and process controls to ensure the consistent production of a PET drug that meets the applicable standards of identity, strength, quality and purity.

Specifically,

1. The (b) (4) identifies the (b) (4) as the finished drug product to be released to the radiopharmacy following completion of required testing and batch release activities. However, (b) (4)

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(b) (4) :

(b)(4)	Product Name
(b)(4)	

2. In addition, SOP QA-000065, Control of Commercial Manufactured Doses, (b) (4) The procedure further (b) (4)

3. Microbiological growth promotion testing was not performed on each lot of microbiological media used for aseptic process simulations (media fills) and environmental monitoring activities. Instead, the firm performs growth promotion testing only once (b) (4). The firm has not established a scientific justification for this practice.

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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."