DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	4/17/2026-4/21/2026* FEI NUMBER 3008486071

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bryan R. Hildebrandt, Facility Manager

FIRM NAME	STREET ADDRESS
SOFIE Co. dba SOFIE	4447 Brass Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75236-2001	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:
FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 1

You did not implement procedures and document your activities in accordance with your procedures to ensure that all equipment is cleaned and suitable for its intended purposes that could reasonably be expected to adversely affect the identity, strength, quality, or purity of a PET drug, or give erroneous or invalid test results when improperly used or maintained.

Specifically,

A.)The (b) (4) hot cell (b) (4) contains a hole in the back wall used for inserting a particle counter probe during environmental monitoring. The firm stated that this hole is part of the manufacturer's original equipment design. However, the firm could not provide Installation Qualification (IQ) documentation demonstrating that the hole was part of the original installation. In addition, when the hole is not in use for environmental monitoring, it is covered with tape (adhesive side facing the chamber interior). The firm has no documentation demonstrating that this practice of covering the hole with tape has been evaluated and approved by the quality unit as an acceptable method for maintaining equipment integrity and preventing contamination.

B.)During observation of the cleaning process on 04/19/2026, the operator did not clean the hole in the back wall of the (b) (4) . The written procedure also does not mention any specific cleaning process for this hole. The (b) (4) operates under negative pressure, thus when the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Youkeun Kim, Investigator	X Youkeun Kim Investigator Signed By: 2002027774 Date Signed: 04-21-2026 09:22:11	4/21/2026

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Bryan R. Hildebrandt, Facility Manager	
FIRM NAME SOFIE Co. dba SOFIE	STREET ADDRESS 4447 Brass Way
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tape is removed for environmental monitoring, accumulated particles and dust from the uncleaned hole area may be drawn into the (b) (4), potentially contaminating materials being transferred. Although materials are transferred via (b) (4) (b) (4), the accumulation of particles in an uncleaned area of equipment used for aseptic operations presents a contamination risk.

***DATES OF INSPECTION**

4/17/2026(Fri), 4/19/2026(Sun), 4/21/2026(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Youkeun Kim, Investigator	X Youkeun Kim Investigator Signed By: 2002027774 Date Signed: 04-21-2026 09:22:11	4/21/2026

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."