DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	4/20/2026-4/24/2026
	FEI NUMBER 3004479507

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kevin H Rhodes, CEO

FIRM NAME	STREET ADDRESS
Fragrance Manufacturing, Inc.	100 Cascade Dr
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18109-9527	TYPE ESTABLISHMENT INSPECTED Manufacterer

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:

OBSERVATION 1

An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.

Specifically,

Your firm failed to conduct ongoing batch testing to ensure a valid stability program. Real time stability checks are only performed during the initial testing phase, resulting in less than one batch per year of drug product being added to the stability program. This deficiency fails to ensure that the product continues to remain stable throughout its shelf life.

OBSERVATION 2

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

A. Your firm failed to establish adequate barriers and environmental controls to prevent potential cross-contamination during manufacturing operations in the compounding (b) (4) warehouse. During the inspection walk through, the following deficiencies were observed: lack of physical barriers and inadequate air handling and environmental controls, such as improper spacing and fan usage during the mixing process.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Azeezat M Lawal, Investigator X Azeezat M Lawal Investigator Signed By: Azeezat M. Lawal -S Date Signed: 04-24-2026 11:43:06	4/24/2026

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B. Your firm lacks a designated area for sampling raw materials and instead conducts sampling in an open warehouse space that lacks structural designs to prevent potential environmental contamination. During the inspection walk through, the following deficiencies were observed: absence of designated sampling area; cleaning supplies were observed in the general area around the sampling drum with no separation of raw material storage; and inadequate environmental controls. In addition, per SOP GEN-0018 *Aseptic Sampling Technique*, there is no mention of a controlled environment where ambient air is not exposed to raw material for potential contamination.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Azeezat M Lawal, Investigator	X Azeezat M Lawal Investigator Signed By: Azeezat M. Lawal -S Date Signed: 04-24-2026 11:43:06	4/24/2026

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."