DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	2/9/2026-2/12/2026
	FEI NUMBER 3021614574

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ramonita Nazario, Vice President of Quality Assurance and Regulatory Affairs

FIRM NAME	STREET ADDRESS
Waylis Therapeutics LLC	2131 Felver Court, Suite B
CITY, STATE, ZIP CODE, COUNTRY Rahway, NJ 07065	TYPE ESTABLISHMENT INSPECTED Corporate Headquaters

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

Written procedures have not been developed for the surveillance of post marketing adverse drug experiences.

Specifically, you have Patient Access and Affordability Programs for 14 out of 15 of your products, but you do not have a procedure for the surveillance of adverse events received by these patient programs. There is also no written procedure for the reconciliation of the adverse events received by any of your Patient Access and Affordability Programs.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Mayar M Mussa, Investigator

X Mayar M Mussa
Investigator
Signed By: 2003950881
Date Signed: 02-12-2026
11:59:33

DATE ISSUED
2/12/2026

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."