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	5/7/2026-5/12/2026*
	FEI NUMBER 2219935

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sandra Lee, Chief Executive Officer

FIRM NAME	STREET ADDRESS
New Jersey Laboratories	1110 Somerset St
CITY, STATE, ZIP CODE, COUNTRY New Brunswick, NJ 08901-3614	TYPE ESTABLISHMENT INSPECTED Control Laboratory

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

Laboratory records do not include the date the sample was taken.

Specifically,

SOP, "QA-027", refers to "Sample Chain of Custody". The sample submission form does not provide requisite sample information to enable the analyst to conduct the test for customer's intended use of the data. For example, the current sample submission form does not include the date the sample was taken. (b) (4), lot# (b) (4) & (b) (4), lot# (b) (4) Tabs were accepted for microbial content testing on 05/05/2026 without the drug product manufacturing or sampling dates.

OBSERVATION 2

Written procedures for cleaning and maintenance fail to include maintenance and cleaning schedules.

Specifically,

A procedure to sanitize, disinfect and maintain the (b) (4) serial number (b) (4) ", (b) (4) used for conducting sterility testing on aseptically prepared dosage forms has not been established. This (b) (4) was used to perform sterility test on samples of at least (b) (4) lots of (b) (4) (b) (4) & (b) (4) vials, between 01/07/2025 and 02/06/2025.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Frederick Razzaghi, Investigator	X Frederick Razzaghi Investigator Signed By: Frederick Razzaghi -S Date Signed: 05-12-2026 15:13:06	5/12/2026

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5/07/2026(Thu), 5/08/2026(Fri), 5/11/2026(Mon), 5/12/2026(Tue)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Frederick Razzaghi, Investigator

X Frederick Razzaghi
Investigator
Signed By: Frederick Razzaghi -S
Date Signed: 05-12-2026
15:13:06

DATE ISSUED
5/12/2026

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."