

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314		DATE(S) OF INSPECTION 8/25/2025-9/5/2025*
		FEI NUMBER 3014229024
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dustin C. DeNeui, Chief Operating Officer		
FIRM NAME North American Custom Laboratories, LLC dba Farmakeio Superior Custom Compounding	STREET ADDRESS 1736 N Greenville Ave	
CITY, STATE, ZIP CODE, COUNTRY Richardson, TX 75081-1808	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drug Products	

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

Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

Specifically,

On 08/25/2025, I observed the following inside your firm's ISO 7 classified buffer room around the ISO 5 laminar flow hood (LFH) used for non-hazardous sterile compounding:

- A) Chipped paint around the HEPA filter directly above the ISO 5 LFH (Asset #0222, (b) (4)),
- B) Peeling/hanging paint on the ceiling tile above the ISO 5 LFH (Asset #0222, S/N (b) (4)), and
- C) A gap in the paneling behind the ISO 5 LFH (Asset #0222, S/N (b) (4)).

According to the PIC, these defects could have been present for at least the last (b) (4) since the previous (b) (4) cleaning performed on 07/24/2025. Between 07/25/2025 and 08/25/2025, approximately (b) (4) lots of sterile compounded drug products were prepared in this compromised environment, including Pyridoxine Hydrochloride/Tirzepatide (25mg/18mg)/mL (2mL) injection, lot LG7642921, beyond use date (BUD) 11/16/2025, compounded on 08/18/2025 and dispensed on 08/25/2025 to a patient in Houma, Louisiana. This sterile drug product was aseptically filled in ISO 5 LFH (Asset #0222, S/N (b) (4))."

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Demario L Walls, Investigator	Demario L. Walls Investigator Signed By: DEMARIO L. WALLS - X Date Signed: 09-05-2025 08:32:22	DATE ISSUED 9/5/2025
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8/25/2025(Mon), 8/26/2025(Tue), 8/27/2025(Wed), 8/28/2025(Thu), 8/29/2025(Fri), 9/02/2025(Tue), 9/03/2025(Wed), 9/04/2025(Thu), 9/05/2025(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Demario L Walls, Investigator	Demario L. Walls Investigator Signed By: DEMARIO L. WALLS - X Date Signed: 09-05-2025 08:32:22	DATE ISSUED 9/5/2025

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."