DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	12/1/2025-12/11/2025* FEI NUMBER 3010166491

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gulshakar Khwaja, RPh, MS, Pharm D., Chief Operating Officer

FIRM NAME	STREET ADDRESS
Nubratori, Inc	381 Van Ness Ave Ste 1507
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Torrance, CA 90501-7220	Outsourcing Facility

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 are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

a. Cleaning validation studies conducted in 2017 relied on media fill activities as a surrogate rather than using residues from actual drug products. Sampling after a media fill does not represent worst-case cleaning conditions for therapeutic compounds and does not demonstrate the effectiveness of the cleaning process in removing active pharmaceutical ingredient (API) residues generated during routine production.

b. Cleaning validation studies conducted in 2017 selected (b)(4) non-sterile (b)(4) as the worst-case product without adequate scientific justification relative to all the sterile injectable drug products manufactured at the facility. Your firm did not appropriately evaluate relevant worst-case factors such as therapeutic potency, solubility characteristics, toxicological properties, and cleaning difficulty of shared equipment, etc. (b)(4) continued to be designated the worst-case product even when new active ingredients were introduced despite the potential for greater cleaning challenges and cross-contamination risks associated with those compounds. For example, in 2019, Lidomar-Lidocaine HCl/Bupivacaine HCl Injection, a (b)(4) product, was introduced in the facility.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lucila B Nwatu, Investigator/Consumer Safety Officer	X Lucila B Nwatu Investigator/Consumer Safety Officer Signed By: LUCILA B. NWATU -S Date Signed: 12-11-2025 10:16:38	12/11/2025

c. In 2025, your firm completed a cleaning verification activity, performing a product exposure evaluation after compounding Lidocidex. This approach is inadequate as cleaning verification can only be performed after successful completion of cleaning validation studies that demonstrate consistent cleaning effectiveness through multiple runs with proper worst-case scenarios and scientific rationale.

Your firm currently manufactures the following sterile drug injectable products:

- Lidocidex I - Dexamethasone Sodium Phosphate/Lidocaine HCl Injection (3.33 mg/1 mL; 6.67 mg/1 mL)
- Lidomar- Lidocaine HCl/Bupivacaine HCl Injection; (10 mg/1 mL; 3.75 mg/1 mL)

OBSERVATION 2

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

a. **Failure to Complete Process Validation for Modified Manufacturing Process:** In 2023, your firm changed the vial filling configuration for Lidocidex I (Dexamethasone Sodium Phosphate/Lidocaine HCl Injection, 3.33 mg/mL; 6.67 mg/mL) from using (b)(4) without performing appropriate process validation studies. Similar vial filling changes were made to Lidomar- Lidocaine HCl/Bupivacaine HCl Injection; (10 mg/1 mL; 3.75 mg/1 mL). Your risk assessment dated 05/01/2023 failed to systematically evaluate critical risks including sterility assurance, filling dynamics, process parameters affecting product quality, and modified aseptic manipulation techniques. This significant process change requires comprehensive process validation to demonstrate that the modified procedure consistently

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	12/1/2025-12/11/2025* FEI NUMBER 3010166491

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Gulshakar Khwaja, RPh, MS, Pharm D., Chief Operating Officer	
FIRM NAME Nubratori, Inc	STREET ADDRESS 381 Van Ness Ave Ste 1507
CITY, STATE, ZIP CODE, COUNTRY Torrance, CA 90501-7220	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

produces drug products meeting predetermined specifications and quality attributes.

b. **Inadequate Use of Media Fill Studies as Substitute for Process Validation:** Your firm conducted media fill studies using (b)(4) with the revised needle configuration instead of performing process validation with actual drug product. Media fill studies alone are insufficient to validate process changes affecting critical quality attributes such as fill volume accuracy, container closure integrity, particulate matter control, and product stability. Process validation must demonstrate that the modified manufacturing process consistently produces the actual drug product with appropriate identity, strength, quality, and purity, which cannot be established through media fill studies that only address sterility assurance.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically:

a. Your 2024 smoke studies do not include simulated set-up of environmental monitoring (EM) plates within the hood to demonstrate that EM preparation activities and plate placement do not compromise unidirectional airflow patterns or create turbulence that could introduce contamination to the critical zone. During my observation of the compounding of Lidocidex I (Dexamethasone Phosphate with Lidocaine HCl (3.33mg/6.67mg/ml), Lot C12032501, I observed personnel preparing EM samples inside the ISO (b)(laminar airflow hood (LAFH) prior to compounding operations, including opening EM plate packaging and labeling plates with non-sterile markers. These activities introduced unnecessary particulate and microbial contamination risks and disrupted unidirectional airflow essential for maintaining sterility. Your procedures fail to define appropriate locations for EM preparation activities, resulting in uncontrolled introduction of non-sterile items into the ISO (b)(4 environment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lucila B Nwatu, Investigator/Consumer Safety Officer	X Lucila B Nwatu Investigator/Consumer Safety Officer Signed By: LUCILA B. NWATU -S Date Signed: 12-11-2025 10:16:38	12/11/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	12/1/2025-12/11/2025*
	FEI NUMBER 3010166491

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Gulshakar Khwaja, RPh, MS, Pharm D., Chief Operating Officer	
FIRM NAME Nubratori, Inc	STREET ADDRESS 381 Van Ness Ave Ste 1507
CITY, STATE, ZIP CODE, COUNTRY Torrance, CA 90501-7220	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

b. During active compounding operations of Lidocidex I (Dexamethasone Phosphate with Lidocaine HCl (3.33mg/6.67mg/ml), Lot C12032501, (b)(4) additional settling plates were stored inside the ISO (b)(4) LAFH beyond the (b)(4) plates permitted in the Batch Production Record. Your 2024 smoke study does not include these additional plates in the ISO (b)(4) hood, demonstrating that your airflow visualization studies do not reflect actual operating conditions.

***DATES OF INSPECTION**

12/01/2025(Mon), 12/02/2025(Tue), 12/03/2025(Wed), 12/04/2025(Thu), 12/05/2025(Fri), 12/08/2025(Mon), 12/09/2025(Tue), 12/11/2025(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lucila B Nwatu, Investigator/Consumer Safety Officer X Lucila B Nwatu Investigator/Consumer Safety Officer Signed By: LUCILA B. NWATU -S Date Signed: 12-11-2025 10:16:38	12/11/2025

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."