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	8/26/2019-9/26/2019* FEI NUMBER 3010166491

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

FIRM NAME	STREET ADDRESS
Nubratori, Inc dba Nubratori Rx	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

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

Specifically,

A) Your firm's most recent smoke study video, filmed on 6/28/2019 of in situ air pattern analysis, was not conducted under dynamic conditions that simulate routine production, such as (b) (4) , IV bag manipulation and injection of drug product into multiple sealed, sterile 5mL clear vials, with (b) (4) (b) (4) Without simulating unidirectional airflow and its sweeping action over and away from a representative operation within the laminar (b) (4) airflow hood, there is no assurance critical processing areas are suitable for aseptic manufacturing of sterile drug products.

B) On 8/28/19, I observed your compounding technician allow vials and tubing lines to be positioned into the path of unidirectional "first air" during the vial filling process of Lidocaine HCl w/Bupivacaine HCl Injection USP, Lot No. C08281901.

C) On 9/24/19, I observed your compounding technician allow gloved hand and vial to be positioned into the path of first air during the vial filling process of Lidocidex 5mg/10mg/1.5mL Injection, Lot No. CO9241901. The (b) (4) HEPA filtered "first air" of the vial's filling surface/septum and needle was disrupted by the technician's gloved finger and vial during needle insertion and during the drawing up of dexamethasone into the syringe.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Zachery L Miller, Investigator X Zachery L Miller Investigator Signed By: Zachery L Miller -S3 Date Signed: 09-26-2019 09:37:36	9/26/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	8/26/2019-9/26/2019* FEI NUMBER 3010166491

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

D) On 9/24/19, I observed your technician wipe down a sterile needle with a sterile (b) (4) prep pad and then proceed to pull up (b) (4) milliliters of lidocaine into a sterile syringe. The (b) (4) mL of lidocaine was later commingled with dexamethasone in a 1,000mL IV bag, in compounding Lidocidex 5mg/10mg/1.5mL Injection, Lot No. CO9241901.

OBSERVATION 2

Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically,

The (b) (4) dwell time of your (b) (4) is neither recorded in a cleaning record nor correctly identified within your (b) (4) Cleaning Procedure of Cleanroom, SOP 4.13.

OBSERVATION 3

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, you compound drug products that: are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

- IFE-PG20 (alprostadil injection)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Zachery L Miller, Investigator	X Zachery L Miller Investigator Signed By: Zachery L. Miller -S3 Date Signed: 09-26-2019 09:37:36	9/26/2019

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	8/26/2019-9/26/2019*
	FEI NUMBER 3010166491

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. Gulshakar Khwaja, RPh, MS, PharmD, Chief Operating Officer

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

*DATES OF INSPECTION

8/26/2019(Mon), 8/27/2019(Tue), 8/28/2019(Wed), 8/29/2019(Thu), 8/30/2019(Fri), 9/23/2019(Mon), 9/24/2019(Tue), 9/25/2019(Wed), 9/26/2019(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Zachery L Miller, Investigator X Zachery L Miller Investigator Signed By: Zachery L. Miller -S3 Date Signed: 09-26-2019 09:37:36	9/26/2019