DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702 ORABIMOW.Correspondence@fda.hhs.gov	6/12/2023-6/22/2023* FEI NUMBER 3015457963

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dongjin Seo, Vice President of Engineering

FIRM NAME	STREET ADDRESS
Neuralink Corporation	7400 Paseo Padre Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fremont, CA 94555-3663	Nonclinical 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 WE OBSERVED:

OBSERVATION 1

Adequate written records are not maintained of all equipment inspection, maintenance, testing, calibrating and/or standardizing operations.

Specifically,

In the case of studies (b) (4) and (b) (4), for equipment used in these studies, records of required maintenance and calibration procedures were not maintained in all cases. For study (b) (4), there is no documentation of calibration and/or maintenance for equipment including:

-pH meter, Asset ID 188 requiring calibration as needed per the instrument manual, no records of calibration were maintained for 2021 and 2022

-(b) (4) Asset ID 163, requiring (b) (4) calibration per SOP Chapter 12, no calibration records were maintained for 2021 and 2022

-Scale, Asset ID 242, requiring (b) (4) calibration per SOP HIS-SOP-600, no calibration records were maintained for 2021 and 2022

-(b) (4) Balance, Asset ID 385, requiring (b) (4) calibration per SOP Chapter 14, no calibration records were maintained for 2021

-(b) (4), Asset ID 75, requiring (b) (4) calibration per SOP ACP-SOP-606, calibration records were not maintained for 2021 and 2022

For study (b) (4), there is no documentation for equipment calibration and/or maintenance for equipment used in the study including:

-(b) (4) Asset ID 130, requiring (b) (4) calibration per SOP Chapter 12, no calibration

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Dongjin Seo, Vice President of Engineering	
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records were maintained for 2021 and 2022
-pH meter, Asset ID 188, requiring (b) (4) calibration per SOP Chapter 14, no calibration records were maintained for 2021 and 2022
-(b) (4) Scale, Asset ID 237, requiring (b) (4) calibration per SOP Chapter 14, no calibration records were maintained for 2021 and 2022
-Vital Signs Monitor, Asset ID 304, requiring (b) (4) calibration and (b) (4) preventative maintenance per SOP Chapter 12, no records were maintained for 2021 and 2022
-(b) (4), Asset ID 338, requiring preventative maintenance per SOP Chapter 14, no maintenance records were maintained for 2021 and 2022
-pH meter, Asset ID 679, requiring (b) (4) calibration per SOP Chapter 14, no calibration records maintained for 2021 and 2022
-pH Meter, Asset ID 715, requiring (b) (4) calibration per SOP Chapter 14, no calibration records were maintained for 2021 and 2022

Additionally, for studies (b) (4) and (b) (4), equipment calibrated by the vendor and delivered with calibration certificates; no vendor certificates/documentation of calibration were maintained for equipment used in the studies including: (b) (4), Alarm Timers/Timers, and Thermometers.

Finally, the Automatic Water Line Decontamination and Maintenance, SOP ACP-D00036 requires system decontamination (b) (4). The performance of the decontamination procedure was not documented for 2021 and 2022.

OBSERVATION 2
The final study report did not include the statement prepared and signed by the quality assurance unit as required by FDA Good Laboratory Practice regulations.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kristin M Abaonza, Investigator Hugh M Mcclure, Investigator Scott B Laufenberg, National Expert	X Hugh M Mcclure Investigator Signed By: Hugh M. Mcclure III -S Date Signed: 06-22-2023 21:28 08	6/22/2023

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For studies (b) (4) and (b) (4), a signed statement prepared by the Quality Assurance Unit (QAU) including the dates that the studies were inspected by the QAU and the dates that the inspection findings were reported to management and the study director, was not included in the final reports for these studies.

OBSERVATION 3

The quality assurance unit failed to determine whether any deviations from approved protocols or standard operating procedures had been made without proper authorization and documentation.

Specifically, per the Animal Care Program procedure, water samples were to be collected for water quality testing (b) (4). There was no documentation of water quality testing for 2022 at the (b) (4) facility. Animals from study (b) (4) were housed at the (b) (4) facility until 15 Sept 2022.

*DATES OF INSPECTION

6/12/2023(Mon), 6/13/2023(Tue), 6/14/2023(Wed), 6/15/2023(Thu), 6/16/2023(Fri), 6/19/2023(Mon), 6/20/2023(Tue), 6/21/2023(Wed), 6/22/2023(Thu)

X Kristin M Abaonza
Investigator
Signed By: Kristin M. Abaonza -S
Date Signed: 06-22-2023 21:28:52

X Scott B Laufenberg
National Expert
Signed By: Scott B. Laufenberg -S
Date Signed: 06-22-2023 21:29:34

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kristin M Abaonza, Investigator Hugh M Mcclure, Investigator Scott B Laufenberg, National Expert	X Hugh M Mcclure Investigator Signed By: Hugh M. Mcclure III -S Date Signed: 06-22-2023 21:28:08	6/22/2023

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."