DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Miriam Ngundi Telephone: 240-402-9774 Industry Information: www.fda.gov/oc/industry	July 22-26, 2024
	FEI NUMBER 3012545799

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Richard Small, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Neurotech Pharmaceuticals, Inc.	900 Highland Corporate Drive, Building #1, Suite #101
CITY, STATE AND ZIP CODE Cumberland, RI 02864	TYPE OF ESTABLISHMENT INSPECTED Drug substance and drug product manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Management with executive responsibility has not ensured that an adequate and effective quality system has been established. For example:

a. Management with executive responsibility has not ensured that the quality policy is established, understood, and maintained at all levels of the organization. Specifically, implementation and training of the quality policy within draft document QM-0001.01 "Neurotech Quality Manual" has not been performed. Additionally, F10404.01 "Quality Policy" was [redacted] (b)(4) " as of June 8, 2021.

b. Management with executive responsibility has not appointed a management representative to ensure that quality system requirements are met, and to report to management on the performance of the quality system. Specifically:
   i. There is no documentation for the appointment of the management representative.
   ii. The management representative is not defined as required to attend the management review meetings as per SOP-1040.03 "Quality Management Review".
   iii. Per SOP-1040.03 "Quality Management Review", the QA Executive Management reviews and approves the presentation on the quality system performance for the management review meetings.

OBSERVATION 2

Inadequate quality oversight to assure that the NT-501 combination product has the identity, strength, quality, and purity it purports or is represented to possess. For example:

a. Written procedures are not followed. For example:
   i. There are no approved quality agreements between Neurotech and suppliers of [redacted] materials including the endothelial serum free media, gripper, scaffold yarn, hollow fiber membrane, titanium anchor loop,1181-M adhesive, and primary container closure as required per SOP-1021.12 "Supplier Qualification & Monitoring".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Miriam Ngundi, Lead Inspector, CSO Alyssa Kitchel, Supervisory Biologist Carolina Panico, Biologist Kyung Sung, Supervisory Biologist	07/26/2024

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ii. On July 23, 2024, it was observed that the operator performing [redacted] of the drug substance did not execute the [redacted] as per SOP-5129.06 "Operation and Maintenance of [redacted]".

iii. On July 23, 2024, it was observed that an operator performed recounting instead of reprocessing of the drug substance formulated [redacted] when the [redacted] was not within the established range, as per SOP-5129.06 "Operation and Maintenance of [redacted]".

iv. On July 24, 2024, it was observed that the operator performing endotoxin testing of the drug product used a [redacted] to collect a sample from the primary container instead of a [redacted], as per [redacted]-2183.06 "Bacterial Endotoxin Testing Using the [redacted]".

b. Written procedures for production and process control are inadequate or not established. For example:

i. SOP-2100.15 "Routine Environmental Monitoring of Aseptic Processing" does not adequately describe the process of how environmental monitoring sampling is to be performed. Specifically, on July 23, 2024, it was observed that [redacted] the encapsulation process, the [redacted] were [redacted] and the air sampling for viable particles was [redacted] in the ISO [redacted] area where [redacted] of primary and secondary packaging occurs. However, [redacted] were [redacted] and no sampling for viable particles was being performed in the adjacent ISO [redacted] area where [redacted] occurs.

ii. SOP-3003.09 "[redacted] PAC [redacted]", SOP-3012.07 "[redacted] of Anchor Loops", and SOP-3104.04 "[redacted] Yarn Cleaning and Processing Method" do not specify that the [redacted] (PAC [redacted], anchor loops, and [redacted] yarn) should be stored in sanitized containers [redacted] to shipment to the [redacted]; however, the operator who performs the [redacted] confirmed that the components should be placed in a sanitized container.

c. Training is inadequate to ensure personnel can independently perform their assigned responsibilities to manufacture the NT-501 combination product. Specifically, on July 23, 2024, it was observed that a trained operator who was performing the [redacted] of capsule batch [redacted] requested instructions for the [redacted] process from another operator executing the [redacted] step.

d. Deviations were not opened [redacted] of the deviation, as per SOP-1013.07 "Quality Event Process".

i. Deviation DEV 00127 for the use of the appearance testing documentation that was "not effective" occurred on March 8, 2023 but was opened [redacted], on [redacted].

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ii. Deviation DEV 00170 for extraneous DNA testing occurred on January 19, 2023 but was opened (b)(4) (b)(4).

iii. Deviation DEV 00256 for the failure of the [redacted] certification of the (b)(4) HEPA filter occurred on November 10, 2023 but was not opened until (b)(4).

e. Documentation practices are insufficient. For example, batch records for the NT-501 combination product do not consistently document all steps that are performed on all nonconforming capsules. Specifically, on July 23, 2024, it was observed that a capsule from batch (b)(4) failed the (b)(4) but was advanced to the (b)(4) (primary packaging) process. The capsule was ultimately rejected. The batch record for batch (b)(4) did not document the [redacted] process that was performed.

OBSERVATION 3

The manual visual inspection program is inadequate to identify turbidity, precipitate, and particulates in the NT-501 combination product. For example:

a. Written procedure to inspect the NT-501 combination product is inadequate or not established.

i. SOP-2188.02 "Visual Inspection of NT-501 Final Product" does not include instructions on how to inspect the parameters (e.g., turbidity, seal leaking, implant seating, precipitates, particles, label) using the (b)(4).

ii. SOP-2188.02 does not specify how operators should set up the visual inspection station to maintain consistent inspection performance. Since the (b)(4) is not adjustable and nor was there an adjustable [redacted], on July 24, 2024, it was observed that an operator was not consistently on the same level as the NT-501 combination product during the manual visual inspection.

b. Written procedures are not followed. Specifically, on July 24, 2024, it was observed that the operator did not [redacted] the product before assessing each parameter as per step 3.2 of SOP-2188.02 "Visual Inspection of NT-501 Final Product".

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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 judgement, 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."