DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	3/3/2025-3/7/2025 FEI NUMBER 3019027610

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shih-Wei Chen, CEO

FIRM NAME	STREET ADDRESS
Aeon Biotherapeutics Corp.	1F & 2F No. 16, Ln. 658 Yingtano Rd., Yingge District
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New Taipei City, 239013 Taiwan	Manufacturer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically, procedures to collect and analyze information, identify and investigate nonconforming product or other quality problems have not been adequately established. For example,

a. Corrective and Preventive Control Procedure, (b) (4)-03-001, Ver. H, Effective: 2024/11/29, does not adequately define input requirements for CAPA initiation. For instance, Process Quality Abnormalities are CAPA inputs that are defined as statistical records of process quality abnormalities exceeding shutdown thresholds during various periods and/or significant quality abnormalities that occur during the process. Your firm has documented only one (1) CAPA since 2018.

Also, Quality Management System Control is a CAPA input that is defined, in part, by occurrences of the same or similar deviation event three times. During review of deviation records from 2019-2023, there were four (4) out of eight (8) occurrences of the same or similar deviation for (b) (4) that were out of (b) (4) calibration. A CAPA for these occurrences was not initiated.

Additionally, during review of three (3) Device History Records from 2023-2024, your firm documented

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nonconforming (b) (4) (component) that was dispositioned as scrap. The quantity of dispositioned component was replaced by a corresponding quantity of accepted component. As such, the defective rate of manufactured finished product is not representative of the manufacturing process.

b. Deviation Management Control Procedure, (b) (4)-03-011, Ver. H, Effective: 2024/11/29, classifies deviation events as (b) (4), which poses a (b) (4); (b) (4), which (b) (4) (b) (4); and (b) (4), which is defined as neither (b) (4) nor (b) (4). Unlike deviation events however, CAPAs are neither classified based on (b) (4) nor does the CAPA procedure establish defined measurable criteria for verification of effectiveness.

c. Risk Evaluation Procedure, (b) (4)-05-005, Ver. M, Effective: 2023/07/14, evaluates risk based on the (b) (4). The core consideration in the (b) (4) however, (b) (4) is not commensurate with manufacturing (b) (4) to evaluate the (b) (4).

d. Non-conforming Product Control Procedure, (b) (4)-03-004, Ver. E, Effective: 2023/07/14, does not adequately define a nonconformance, and the requirements for non-conforming product as an input to a CAPA.

OBSERVATION 2
Products that do not conform to specifications are not adequately controlled.

Specifically, your firm's management of rejected product is not controlled to ensure material is adequately dispositioned and documented.

During a walkthrough of the facility on 2025/03/06, (b) (4) of (b) (4) (Material Number (b) (4), Lot (b) (4)), was staged in the rejected products area. The Return Notice Form dated

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2023/12/22 was stored with the rejected (b) (4) . A review of Return Notice Forms of nonconforming materials was conducted from 2023-2024. (b) (4) additional lots of nonconforming (b) (4) were identified to be returned. The (b) (4) lots rejected on (b) (4) (b) (4) had been returned to the supplier, but this was not documented in their respective Return Notification Forms.

OBSERVATION 3

Procedures to prevent contamination of equipment or product by substances that may have an adverse effect on product quality have not been adequately established.

Specifically, your firm's gowning procedure does not adequately define significant hygiene activities related to donning cleanroom garments. Cleanroom Gowning Operation Procedure, (b) (4) -04-007, Ver. E, Effective: 2023/07/14, does not specify a designated time for hand washing and allows for the individual to (b) (4) .

Employee (b) (6), (b) (was observed on 2025/03/06 entering the gowning room without following the firm's procedure. The order of activities observed include inadequate use of the cleanroom (b) (4) , (b) (4) , (b) (4) , (b) (4) , (b) (4) , (b) (4) , (b) (4) , and (b) (4) cleanroom. The procedure requires the employee to (b) (4) , (b) (4) , (b) (4) , (b) (4) , (b) (4) , and (b) (4) .

OBSERVATION 4

Procedures for (b) (4) of nonconforming product have not been adequately established.

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Specifically, your firm's procedure Product Manufacture Procedure, (b) (4) -04-005, Ver. F, Effective: 2023/07/14, specifies (b) (4) for packaging and labeling of shipping and storage containers. However, (b) (4) for nonconforming product is assessed on (b) (4) and (b) (4) without defining the criteria for (b) (4) and to assess whether (b) (4) includes (b) (4) and (b) (4) of nonconforming product (b) (4) (b) (4) to ensure the product meets its current approved specifications.

During review of (b) (4) Device History Records of autologous platelet-rich plasma (PRP) kits, the manufacturing record documents (b) (4) of (b) (4) -03-024-(b) (4) and (b) (4) Record, (b) (4) -03-051- (b) (4) and (b) (4) Record, and (b) (4) -03-062- (b) (4) and (b) (4) Record, as identified options to (b) (4) during the stage of manufacturing.

X _____

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

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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 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."