DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration Center for Biologics Evaluation and Research - Document Control Center 10903 New Hampshire Avenue, WO71 - G112 Silver Spring, MD 20993-0002 240-402-8360 Industry Information: www.fda.gov/oc/industry	November 19-21, 2024
	FEI NUMBER 3027619751

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kefaya Amer, Director of Regulatory Affairs and Quality

FIRM NAME	STREET ADDRESS
ABO Holdings, Inc.	2949 Coronado Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
San Diego, California 92154	Plasmapheresis Center

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) (WE) OBSERVED:

Observation 1: The firm did not correctly perform the Performance Qualification studies for the (b)(4) (b)(4) Centrifuges in use at the establishment. Specifically, when selecting the (b)(4) assay values from the manufacturer package insert, the firm selected assay values intended for (b)(4) instruments using (b)(4) (b)(4) The firm should have selected the assay values intended for (b)(4) Centrifuges using (b)(4). The correct assay values are listed in a different table on the same manufacturer package insert. The acceptable ranges for the reference control material are significantly different for the (b)(4) of instruments. The (b)(4) Centrifuges are used in the qualification of donors. Proper execution of Performance Qualification is necessary to demonstrate the instruments perform as intended and to ensure compliance with Source Plasma manufacturing requirements.

Observation 2: The firm is not testing each donation for evidence of infection due to relevant transfusion transmitted infections (RTTI). Specifically, when a donor tests reactive for an RTTI on one donation, additional donation(s) made after that donation and prior to the time the donor is permanently deferred are not tested for RTTI. Samples from some subsequent donations are not shipped to the firm's contact testing laboratory after a reactive test result is obtained and testing orders are cancelled. Blood establishments that collect blood and blood components for use in further manufacturing must test each donation for evidence of infection due to RTTI. For example:

a. Donor # [redacted] tested [redacted] on donation # [redacted], collected [redacted]. The donor's subsequent donation, # [redacted], collected on [redacted], was not tested for RTTI because the samples from that donation were not shipped to the testing laboratory.

b. Donor # [redacted] tested [redacted] on donation # [redacted], collected [redacted]. The donor's subsequent donation, # [redacted], collected on [redacted], was not tested for RTTI because the samples from that donation were not shipped to the testing laboratory.

c. Donor # [redacted] tested [redacted] on donation # [redacted] collected [redacted]. The donor's subsequent [redacted] donations, # [redacted], collected on [redacted], and # [redacted], collected on [redacted],

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Carmelita F. Bibby, Consumer Safety Officer	11/21/2024

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were not tested for RTTI because the samples from these donations were not shipped to the testing laboratory.

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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."

Carmelita F. Bibby -S

Digitally signed by Carmelita F. Bibby -S
Date: 2025.01.13 19:45:02 -05'00'