Michelle D. Gutierrez -S

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Date: 2024.03.13 13:22:14 -04'00'

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 10903 New Hampshire Avenue Silver Spring, MD 20993-0002 Phone Number: 240-402-8360 Industry Information: www.fda.gov/oc/industry	October 17-19, 2023
	FEI NUMBER 3026578734

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Robert Fredrickson, Regional Quality Lead

FIRM NAME	STREET ADDRESS
BioLife Plasma Services L.P.	4456 Ming Avenue
CITY, STATE AND ZIP CODE Bakersfield, CA 93309	TYPE OF ESTABLISHMENT INSPECTED Source Plasma Collection 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) (WE) OBSERVED:

The firm does not always provide all screening and additional/supplemental/confirmatory test results obtained from testing for evidence of infection due to relevant transfusion-transmitted infection(s) (RTTI) that were the basis for deferral of the donors. The firm must provide the donor with results of all tests for evidence of infection due to RTTIs, including non-reactive results for the same marker and results of further testing on the test reactive index donation and subsequent donations.

According to the firm, changes to the donor notification process, to notify donors of all subsequent units with test results for the same reactive marker that was the reason for deferral, was implemented on June 26, 2023.

a. donor (b) (6), (b) (7)(C) initially tested reactive for HBsAg on collection (b) (6), (b) (7)(C), collected on (b) (6), (b) (7)(C). The donor had a subsequent donation on (b) (6), (b) (7)(C), collection (b) (6), (b) (7)(C), however the firm only notified the donor of the test reactive index donation and not the subsequent donation.

b. donor (b) (6), (b) (7)(C) initially tested reactive for HCV on collection (b) (6), (b) (7)(C), collected on (b) (6), (b) (7)(C). The donor had a subsequent donation on (b) (6), (b) (7)(C), collection (b) (6), (b) (7)(C), however the firm only notified the donor of the test reactive index donation and not the subsequent donation.

c. donor (b) (6), (b) (7)(C) initially tested reactive for HCV on collection (b) (6), (b) (7)(C), collected on (b) (6), (b) (7)(C). The donor had a subsequent donation on (b) (6), (b) (7)(C), collection (b) (6), (b) (7)(C), however the firm only notified the donor of the test reactive index donation and not the subsequent donation.

Add Continuation Page

SEE REVERSE OF THIS PAGE

/S/

EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
Michelle Gutierrez Consumer Safety Officer, CBER/OBRR	10/19/2023

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 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."