DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	3/24/2026-3/26/2026
	FEI NUMBER 1073283

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Laura M. Ashline, Donor Services Manager

FIRM NAME	STREET ADDRESS
OneBlood, Inc.	224 Barton Blvd. Ste. 204
CITY, STATE, ZIP CODE, COUNTRY Rockledge, FL 32955-2742	TYPE ESTABLISHMENT INSPECTED Blood Donor 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 OBSERVED:

OBSERVATION 1

Failure to submit a biological product deviation report.

Specifically,

1. Donor (b) (4), (b) (6), (b) (7)(C) was identified as a (b) (6), (b) (7)(C) donor and was determined to be ineligible on 02/25/2024. However, on (b) (6), (b) (7)(C), the donor was permitted to make (b) (6), (b) (7)(C) donations, resulting in the manufacture of (b) (6), (b) (7)(C) Double Red Blood Cell (RBC) units.

   Subsequently, on (b) (6), (b) (7)(C), these RBC units were distributed for transfusion.

   You failed to identify these events as reportable and did not submit Biological Product Deviation (BPD) reports as required.

2. Donor (b) (4), (b) (6), (b) (7)(C) disclosed that (b) (6), (b) (7)(C) was (b) (6), (b) (7)(C) donor on 12/30/2021 and was therefore ineligible for (b) (6), (b) (7)(C) donation. However, the donor was permitted to donate on (b) (6), (b) (7)(C), resulting in the manufacture of (b) (6), (b) (7)(C) Red Blood Cell (RBC) units.

   Subsequently, on (b) (6), (b) (7)(C), these RBC units were distributed for transfusion. The donor was not determined to be ineligible until 09/30/2024.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Mizanne E Lewis, Investigator

X Mizanne E Lewis
Investigator
Signed By: MIZANNE E. LEWIS -S
Date Signed: 03-26-2026 12:01:20

DATE ISSUED
3/26/2026

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You failed to identify these events as reportable and did not submit Biological Product Deviation (BPD) reports as required.

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."