DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	6/30/2025-7/3/2025
	FEI NUMBER 1470270

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lisa A. Bender, Director-Donor Services

FIRM NAME	STREET ADDRESS
ImpactLife	1408 W University Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Urbana, IL 61801-2341	Community Non Hospital Blood Bank

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

Written reports of investigations of adverse reactions, including conclusions and follow up, are not prepared and maintained.

Specifically,

Your SOP 1500 "Management of Reactions" effective date October 2nd 2023, states that reactions should be documented in your blood electronic system (b) (4) or in the DHQ if (b) (4) is not available.

You failed to document and investigate all reported donor adverse events. For example, while reviewing the donor adverse event reports for donor (b) (4), (b) (6), (b) (7)(C) event date (b) (4), (b) (6), (b) (7)(C) and the report for donor (b) (4), (b) (6), (b) (7)(C) event date (b) (4), (b) (6), (b) (7)(C) it was noted both events were marked as severe however, no further details of the location of the event, event type, donor symptoms, or donor treatment were documented. For both instances minor error reports, MER (b) (4), (b) (6), (b) (7)(C) and MER (b) (4), (b) (6), (b) (7)(C) were created to acknowledge the documentation deviations with the employees involved however, no further investigations with the employees involved was conducted pertaining to the details of the donor adverse events.

Additionally, while reviewing donor complaint DC-250413-02 which was received on (b) (4), (b) (6), (b) (7)(C) it was noted that donor (b) (4), (b) (6), (b) (7)(C) experienced a bruise and pain in their arm at their last donation however, no donor adverse event report was created. While reviewing donor complaint DC-230517-01 which was received on (b) (4), (b) (6), (b) (7)(C) it was noted that donor (b) (4), (b) (6), (b) (7)(C) stated that they had passed out after their last donation. however, no donor adverse event report was created.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Zoey A Trombley, Investigator X Zoey A Trombley Investigator Signed By: Zoey A. Trombley -S Date Signed: 07-03-2025 10:08:09	7/3/2025

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EMPLOYEE(S) SIGNATURE

Zoey A Trombley, Investigator

X Zoey A Trombley
Investigator
Signed By: Zoey A Trombley -S
Date Signed: 07-03-2025
10:08:09

DATE ISSUED
7/3/2025

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."