DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	5/8/2025-5/9/2025
	FEI NUMBER 3015522161

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Emilie S. Webb, Manager, Reference Laboratory

FIRM NAME	STREET ADDRESS
ImpactLife	6330 Copps Ave Unit A
CITY, STATE, ZIP CODE, COUNTRY Monona, WI 53716-3721	TYPE ESTABLISHMENT INSPECTED 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 standard operating procedures including all steps to be followed in the storage and distribution of blood and blood components for allogeneic transfusion were not always followed.

Specifically,

Your standard operating procedure SOP 8222 entitled "Inventory Management Distribution: Relocation Function" requires you to perform visual inspection of all products upon receiving relocated products [redacted] them into your computer electronic system. On 05/08/2025, three Red Blood Cells units #W038325042201, #W038325021203, #W038325073328 were received at your facility and scanned into your computer electronic system. There was no visual inspection performed for the above units but visual inspection of these blood products was documented as acceptable.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Irina Gaberman, Investigator X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 05-09-2025 08:58:14	5/9/2025

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."