DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	4/27/2026-4/29/2026
	FEI NUMBER 3025612837

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Duane E. Day, Owner and President

FIRM NAME	STREET ADDRESS
DONOVIVO, LLC	46430 Peary Court
CITY, STATE, ZIP CODE, COUNTRY Novi, MI 48377-1732	TYPE ESTABLISHMENT INSPECTED 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

For products not intended for transfusion, the container label fails to contain the statement "Caution: For Use in Manufacturing Noninjectable Products Only" or other cautionary statement approved by CBER.

Specifically, since (b) (4) your firm has collected approximately (b) (4) units of whole blood not intended for transfusion. Your firm does not label the collection (b) (4) with a statement for intended use.

OBSERVATION 2

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

Specifically, since (b) (4) your firm has collected approximately (b) (4) units of whole blood. Your firm documented 21 blood donor adverse events but failed to create a written investigation with a conclusion and followup. Adverse events include 15 instances of "faint," 1 instance of "nauseous," 1 instance of "got sick," 1 instance of "queasy," and 3 instances of "sick after donation." Your firm has no additional documentation for these adverse events.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Matthew J Gretkierewicz, Investigator

X Matthew J Gretkierewicz Investigator Signed By: MATTHEW J. GRETKIEREWICZ -S Date Signed: 04-29-2026 08:11:10

DATE ISSUED
4/29/2026

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."