DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	5/30/2025-6/5/2025* FEI NUMBER 3015989022

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tyson L. Hale, Center Director

FIRM NAME	STREET ADDRESS
Octapharma Plasma Inc.	2125 Oddie Blvd
CITY, STATE, ZIP CODE, COUNTRY Sparks, NV 89431-3563	TYPE ESTABLISHMENT INSPECTED Source Plasma Collection Establishment

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 determine the eligibility of a donor of blood or blood components before collection.

Specifically:

1. Donors are not assessed for an irregular pulse on the day of their donation and prior to collection to ensure the donor's health is not adversely affected by the Source Plasma collection.
2. Donors whose pre-donation blood pressure measurement is determined to be outside the acceptable ranges of 90-180 mm Hg systolic or 50-100 mm Hg diastolic are not deferred from donation, nor are they referred to the responsible physician.
3. Donors whose pre-donation pulse measurement is determined outside the acceptable range of between 50 and 100 beats per minute are not deferred from donation, nor are they referred to the responsible physician.

Your firm collected plasma from (b) (4) donors in 2025 so far, in 2024 you collected plasm from (b) (4) donors, and in 2023 you collected plasma from (b) (4) .

OBSERVATION 2

The standard operating procedure fails to include written descriptions of methods for performing donor qualifying tests and measurements, including minimum and maximum values for a test or procedure when a factor in determining acceptability.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shelley H Beausoleil, Investigator	X Shelley H Beausoleil Investigator Signed By: Shelley H. Beausoleil - S Date Signed: 06-05-2025 13:04:02	6/5/2025

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Specifically, your firm does not have written procedures in place to assess donors for irregular pulse on the day of collection and prior to donation.

***DATES OF INSPECTION**
5/30/2025(Fri), 6/02/2025(Mon), 6/03/2025(Tue), 6/04/2025(Wed), 6/05/2025(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shelley H Beausoleil, Investigator	X Shelley H Beausoleil Investigator Signed By: Shelley H. Beausoleil - S Date Signed: 06-05-2025 13:04:02	6/5/2025

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."