DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration Center for Biologics Evaluation and Research - Document Control Center 10903 New Hampshire Avenue, WO71 - G112 Silver Spring, MD 20993-0002 240-402-8360 Industry Information: www.fda.gov/oc/industry	June 21-23, 2023
	FEI NUMBER 3023372291

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jason Swenson, Corporate Director of Quality

FIRM NAME	STREET ADDRESS
Join Parachute, LLC	2301 East Race Avenue
CITY, STATE AND ZIP CODE Searcy, Arkansas 72143	TYPE OF ESTABLISHMENT INSPECTED Source Plasma Collection Facility

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) (WE) OBSERVED:

Observation 1

Reinstatement of donors into the plasmapheresis program deferred for abnormal Serum Protein Electrophoresis (SPE)/Total Protein test results are not performed by a Responsible Physician (RP) licensed to practice medicine in the jurisdiction where the collection establishment is located. Specifically, the (b) (4) also known as the (b) (4) who is not licensed to practice medicine in the state of Arkansas, reinstated the following deferred donors:

a. Donor Number: (b) (4), (b) (6), (b); Donation Date: (b) (6), (b) (7)(C); Date of Deferral: (b) (6), (b) (7)(C); Date of Sample Only Collection: (b) (6), (b) (7)(C); Date of Reinstatement: (b) (6), (b) (7)(C)

c. Donor Number: (b) (4), (b) (6), (b); Donation Date: (b) (6), (b) (7)(C); Date of Deferral: (b) (6), (b) (7)(C); Date of Sample Only Collection: (b) (6), (b) (7)(C); Date of Reinstatement: (b) (6), (b) (7)(C).

b. Donor Number: (b) (4), (b) (6), (b); Donation Date: (b) (6), (b) (7)(C); Date of Deferral: (b) (6), (b) (7)(C); Date of Sample Only Collection: (b) (6), (b) (7)(C) Date of Reinstatement: (b) (6), (b) (7)(C)

Add Continuation Page

SEE REVERSE OF THIS PAGE /s/

DATE ISSUED
6/23/2023

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS

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 judgement, 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."

Catherine L. Mcgraw -S

Digitally signed by Catherine L. Mcgraw -S
Date: 2023.08.18 08:39:42 -04'00'