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	February 25, 2025 - February 27, 2025
	FEI NUMBER 3022728365

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Luke Winter, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Join Parachute, LLC	3521 7th Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bay City, TX 77414	Plasmapheresis 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) (WE) OBSERVED:

1. Facilities must provide adequate space to perform manufacturing operations, including the performance of health history evaluations and screening tests to determine donor eligibility The (b)(4) contains at (b)(4) with associated (b)(4), with proposed space for three (b)(4). There are also (b)(4) that are used for counseling/ questioning donors and performing examinations. We found the following deficiencies in our inspection of the [redacted]:

a. There is no additional space available for donors to review information provided (b)(4) or to complete the Donor History Questionnaire using the firm's (b)(4). As a result, the donors (b)(4), while staff and other donors are in [redacted] (b)(4) the area and talking freely in the (b)(4). As a result, there is no privacy provided for donors to consider the DHQ questions and their responses.

b. Donors must (b)(4) while being screened as there is no other space available, so there is no privacy afforded to donors who may be deferred.

2. Facilities must provide adequate lighting and ventilation to facilitate operations. The area in the [redacted] used for conducting donor health history reviews/questioning, physical examinations and to administer the informed consent does not have adequate outside ventilation in the area ([redacted]) to maintain a comfortable environment for donors or employees when the door is closed for any length of time, such as when conducting counseling or physicals. The area becomes unacceptably warm and uncomfortable very quickly.

3. The firm logged one deviation (NCR-24-8114-8027) because in-house units collected from an [redacted] reactive and confirmed [redacted] donor during the (b)(4) "look back" period (b)(4) the donor's reactive screening and confirmatory tests which occurred on or about (b)(4), were not quarantined and destroyed within [redacted] the donor's test results were obtained. The donor donated a total of (b)(4) during the lookback period and the [redacted] unit). (b)(4) had been (b)(4) and were recovered through the (b)(4) look back

SEE REVERSE OF THIS PAGE	(b)(4)	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Racquel East, CSO, CBER/OBRR/DBCD/BPB Barbara Peoples, CSO, CBER/OBRR/DBCD/BPB	02/27/2025

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notification process. However, staff failed to quarantine [redacted] additional units that were still in storage at the center. These units were discovered in [redacted], likely because they were selected for shipment and were found to have unacceptable test results. It was unclear from the documentation of the firm's investigation 1) why staff failed to quarantine and destroy all of the in house units within [redacted] of the donor's reactive [redacted] results as required; 2) why the quality review failed to identify that the in-house units had not been quarantined and destroyed; and 3) why appropriate preventative and corrective action was not taken at the time to prevent this type of error from occurring again. The employees responsible for these errors no longer are employed by the firm; however, the firm has yet to determine if their SOPs are adequate to ensure that appropriate actions are taken to secure and destroy in-house units donated during a look back period.

4. On [redacted], donor [redacted] NDDR check was deemed unacceptable (NDDR [redacted] - exact match). However, the donor was not deferred in the [redacted] system at the time and remained eligible to donate in the firm's [redacted] until this was discovered on [redacted]. The NDDR check is performed on the donor's first donation and on any subsequent donation when the donor receives a physical. The Chief Operating Officer stated that this donor would have been unable to donate if [redacted] had presented again because another NDDR check would have needed to be performed.

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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."

Racquel N. East -S Digitally signed by Racquel N. East -S
Date: 2025.03.09 16:05:24 -04'00'