

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

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

DATE(S) OF INSPECTION

March 19 - 21, 2019

FEI NUMBER

3014545171

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Maxwell Hunter, Plasma Quality Director (Interim)

FIRM NAME

KEDPLASMA LLC

STREET ADDRESS

6445 Old National Highway

CITY, STATE AND ZIP CODE

Atlanta, Georgia 30349

TYPE OF ESTABLISHMENT INSPECTED

Plasmapheresis

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. The firm does not always make reasonable attempts to notify donors who are deferred based on the results of tests for evidence of infection with a relevant transfusion transmissible infection of all the results of the tests that were the basis for deferral. Specifically,

Donor (b) (6), (b) (7)(C) was deferred for a positive Anti-HCV and "HCV ELISA" supplemental test and a positive syphilis screen and syphilis confirmatory test. The donor was notified of the results as described below:

- Letter sent on 11/19/2018 contained the following results: Anti-HCV (results received 11/15/2018) and HCV ELISA (results received 11/19/2018); mailing was successful.
- Telephone calls on 11/21/2018 and 11/28/2018 were both unsuccessful
- Letter sent on 11/28/2018 contained the following results: Syphilis (b) (4) (results received 11/15/2018) and Syphilis Confirmatory (results received 11/21/2018); mailing was unsuccessful.

The firm was aware of the syphilis screening test results but did not include them in the notification packet successfully sent on 11/19/2018; therefore, the donor was not notified of these results.

2. The firm does not always follow their written standard operating procedures for all steps in the manufacture of Source Plasma and for recordkeeping related to good manufacturing practices. For example:

a. SOP 13.1: Receipt Review of Unsuitable Test Results requires units collected from donors with reactive test results to be culled within (b) (4) of receipt of reactive test results and reclassified to the waste status. While reviewing the records of units with reactive test results on 3/19/2019, we observed that 4 of 79 reactive units (described below) had not been culled and reclassified according to the SOP.

- (b) (4) – Anti-HIV-1/2 Positive (results received 1/24/2019)
- (b) (4) – Anti-HIV-1/2 Positive (results received 1/31/2019)
- (b) (4) – Syphilis Positive (results received 3/16/2019)
- (b) (4) – Syphilis Positive (results received 3/2/2019)

SEE
REVERSE
OF THIS
PAGE

/S/

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Judy Ellen Ciaraldi, Consumer Safety Officer,
CBER
Christopher Cox, Consumer Safety Officer, CBER
Cordelia J. Brammer, Investigator, ORA

DATE ISSUED

March 21, 2019

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Food and Drug Administration Center for Biologics Evaluation and Research - Document Control Center 10903 New Hampshire Avenue, WO71 - G112 Silver Spring, MD 20993-0002 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION March 19 - 21, 2019
	FEI NUMBER 3014545171

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Maxwell Hunter, Plasma Quality Director (Interim)

FIRM NAME KEDPLASMA LLC	STREET ADDRESS 6445 Old National Highway
CITY, STATE AND ZIP CODE Atlanta, Georgia 30349	TYPE OF ESTABLISHMENT INSPECTED Plasmapheresis

b. SOP 21.25: (b) (4) states the (b) (4) device check includes ensuring the blood pressure cuff is properly attached to the device, is clean and in working condition. While observing donor screener (b) (6), (b) (7)(C) perform the (b) (4) quality control of the donor screening equipment, we noticed that the cuffs were not attached to the (b) (4) vital sign monitors and were not included in the (b) (4) device check procedures. Donor screener (b) (6), (b) (7)(C) also did not inspect the cuffs to determine if they were clean and in working condition.

c. According to SOP 19.1: Donor Adverse Events and Reports, moderate and severe donor adverse events are documented on a Donor Adverse Event Report (DAER) for further investigation, medical follow-up, and/or and Corrective/Preventative Action documentation (CAPA).

i. Page 12 of 12, table 10 states in part, "The original completed DAER, associated SDAER, and the Physician/Physician Substitute Activity Report, if applicable, is filed under all other documents on the right side of the associated DRF." Donor (b) (6), (b) (7)(C) experienced a moderate donor reaction on (b) (6), (b) (7)(C) and Donor (b) (6), (b) (7)(C) experienced a moderate donor reaction on (b) (6), (b) (7)(C). The DAERs were not in the donors' report file (DRF).

ii. Page 4 of 12, section 2.1 states in part, "As early as feasible, reasonable attempts are made to contact donors who have had a moderate or severe DAE." Donor (b) (6), (b) (7)(C) experienced a moderate donor reaction on (b) (6), (b) (7)(C). The Medical Director, Physician Substitute, Center Manager, and a member of the Quality Assurance unit (QAU) reviewed the DAER on 3/18/2019. The section of the DAER designated for documentation of the follow-up with the donor was left blank. The center did not record the time/date, initials, and outcomes as well as attempts to contact the donor after the donor's reaction.

iii. Page 11 of 12, table 8, step 2 states in part, "Within one working day of Medical Director evaluation/ signature on the DAER, the Physician Substitute reviews and initiates actions per Medical Director instructions.*** Check appropriate box and enter initials/date after the Medical Director's instructions have been completed and recorded in DMS/DRF." Donor (b) (6), (b) (7)(C) experienced a moderate donor reaction on (b) (6), (b) (7)(C). The Medical Director reviewed the DAER on 12/12/2018. The section of the DAER designated for documentation of the Physician Substitute's initials, date, and the checked box, after the Medical Director's instructions have been completed, was left blank.

SEE
REVERSE
OF THIS
PAGE

/S/

EMPLOYEE(S) NAME AND TITLE (Print or Type) Judy Ellen Ciaraldi, Consumer Safety Officer, CBER Christopher Cox, Consumer Safety Officer, CBER Cordelia J. Brammer, Investigator, ORA	DATE ISSUED March 21, 2019
--	-------------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Food and Drug Administration Center for Biologics Evaluation and Research - Document Control Center 10903 New Hampshire Avenue, WO71 - G112 Silver Spring, MD 20993-0002 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION March 19 - 21, 2019
240-402-8360		FEI NUMBER 3014545171
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Maxwell Hunter, Plasma Quality Director (Interim)		
FIRM NAME KEDPLASMA LLC	STREET ADDRESS 6445 Old National Highway	
CITY, STATE AND ZIP CODE Atlanta, Georgia 30349	TYPE OF ESTABLISHMENT INSPECTED Plasmapheresis	

iv. Page 11 of 12, table 9, step 1 and 2 states in part, "The completed DAER is reviewed by the Physician Substitute who signs and dates in the space provided. The Physician Substitute provides the DAER to Center Management and QAU Member for closure review. *** Within 30 days of the event date a QAU Member closes the completed DAER and the corresponding DAE Issue." Donor (b) (6), (b) (7)(C) experienced a moderate donor reaction on (b) (6), (b) (7)(C). The Medical Director reviewed the DAER on 10/25/2018. Section IX of the DAER, designated for DAER closure review was signed by the Physician Substitute on 11/8/2018. The space designated Center Management, Laboratory Director, and QAU Member review was left blank. Today's date of 3/21/2019 is (b) (6), (b) (7)(C) calendar days since the event date of (b) (6), (b) (7)(C). This is beyond the 30-day requirement that a QAU Member closes the completed DAER.

d. SOP 18.8: Donor Notification and Counseling states the notification packet is sent by certified mail first and a telephone call is only initiated if the mailing was unsuccessful. The Donor Counseling Acknowledgement form for donor (b) (6), (b) (7)(C), who is HCV positive, states the donor was notified of the results as described below:

- 11/13/2018 – Telephone call was unsuccessful
- 11/17/2018 – Notification packet mailing was successful

There is no explanation why the activities were not performed in the order specified in the SOP.

SEE REVERSE OF THIS PAGE	/S/	EMPLOYEE(S) NAME AND TITLE (<i>Print or Type</i>) Judy Ellen Ciaraldi, Consumer Safety Officer, CBER	DATE ISSUED March 21, 2019
		Christopher Cox, Consumer Safety Officer, CBER Cordelia J. Brammer, Investigator, ORA	

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."