



Food and Drug Administration  
Kansas City District  
Southwest Region  
11630 West 80<sup>th</sup> Street  
Lenexa, Kansas 66214-3340  
Telephone: (913) 752-2100

March 3, 2003

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER  
Ref. KAN-2003-07**

Dennis G. Young  
Vice President, Plasma Sourcing  
BioLife Plasma Services, L.P.  
One Baxter Way  
Westlake Village, CA 91362

Dear Mr. Young:

During an inspection of your plasmapheresis center, located at 1602 North Woodbine Street, St. Joseph, Missouri on January 13 to 28, 2003, our investigators documented deviations from Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components and finished pharmaceuticals under Title 21, *Code of Federal Regulations* (CFR), Parts 210-211 and 600-680.

Our investigators documented deficiencies relating to your firm's failure to follow written standard operating procedures (SOPs) [21 CFR 211.100 and 606.100].

1. Specifically, employees did not always follow instructions in the Autopheresis-C Plasmapheresis Operator's Manual (Topic 2 Safety, pg. 2.10) which provides instructions on what to do when red cells/hemoglobin is confirmed in the reservoir. For example:
  - On three separate dates in October and December, 2002, three donations led to destruction of the plasma units due to the presence of red cells in the bottles. At least one of the donations had red cells returned to the donor. The remaining two donations were documented as "No RBC loss", which may indicate red cells were also returned.

Deficiencies were also documented relating to your firm's training of personnel responsible for the collection of blood or blood components [21 CFR 606.20(b) and 211.25(a)].

1. Employee training for hemoglobin detect alarms has not included the safety risks involved with returning hemolyzed cells to donors, or the skills necessary to identify hemolyzed cells during a donation.
2. Certain employees who were interviewed could not provide the correct procedure to follow when red blood cells/hemoglobin is observed in the plasma line or bottle.

Your firm reported three Blood Product Deviation reports to the U.S. Food and Drug Administration (FDA), between May 4 and October 8, 2002, in excess of 45 days of discovering the events [21 CFR 606.171(c)].

The above deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all source plasma produced and issued by your plasmapheresis centers is in compliance with the Act and with the CGMP regulations. You should take prompt action to correct these deviations. Your failure to correct these deviations may result in regulatory action being taken by FDA without further notice. Possible actions include license suspension and/or revocation, seizure, and/or injunction.

We are in receipt of a letter from Mr. John K. McVey, dated February 3, 2003, which is his response to the inspectional observations discussed with personnel at the conclusion of the inspection. We have reviewed this response, and note Mr. McVey has committed to a number of corrective actions to address the observations, including re-training of current staff, internal audits at centers that use the Autopheresis-C instrument, and implementation of a Corrective Action/Preventive Action plan to address the timely reporting of Blood Product Deviations.

In addition, we have the following specific comment on the response to Observation #2:

This observation concerned employee training regarding hemoglobin detect alarms, not including the safety risks involved with returning hemolyzed cells to donors, and the interview of four employees who could not provide the correct procedure. Mr. McVey's response to this was, in part, "*The Management Team expressed concern that the observation may be somewhat misleading.*"

During the closeout meeting at the conclusion of the inspection, our investigator informed those present (including Mr. McVey by teleconference) that four employees were interviewed during the course of the inspection. Relevant remarks obtained during those interviews were documented in Affidavits which management refused to read or sign. The investigator stated that none of the three Phlebotomists could recite the proper procedure for

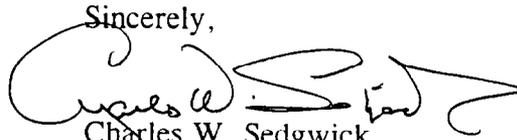
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Vice President Plasma Sourcing  
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handling a hemoglobin detect alarm. Their responses either compromised an incorrect method, or continuation of the donation without investigation. The Processing Technologist stated she was unaware that the Bayer acceptance chart was to be used on frozen plasma, or that lipemic plasma was to be destroyed.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these deviations, in addition to those covered in Mr. McVey's February 3 letter. If you cannot complete corrections within 15 working days, state the reason for the delay and the time period within which corrections will be completed.

Your reply should be addressed to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick", with a large, sweeping flourish extending to the right.

Charles W. Sedgwick  
District Director  
Kansas City District

cc: Sharon L. Weston  
Center Manager  
BioLife Plasma Services L.P.  
1602 N. Woodbine St.  
St. Joseph, MO 64506

John K. McVey, Senior Director  
Quality Assurance & Regulatory Affairs  
BioLife Plasma Services L.P.  
1435 Lake Cook Road  
Deerfield, IL 60015