



Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
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April 22, 2003

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-18

Barry D. Plost  
Chief Executive Officer  
Biologics Division  
Biomat USA, Inc.  
1925 Century Park East, #920  
Los Angeles, California 90067

**WARNING LETTER**

Dear Mr. Plost:

During an inspection of your plasmapheresis center, located at 101 North Union Street, Suite 108, Kennewick, Washington, on March 11-14, and 18-21, 2003, our investigator documented deviations from Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 351(a)(2)(B)) and the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components under Title 21, Code of Federal Regulations (CFR), Parts 600-680. You can find the Act and other regulations through links in FDA's home page at <http://www.fda.gov>.

The observed deviations include the following:

1. Normal Source Plasma units with reactive screening tests for evidence of infection, or a previous record of a reactive screening test for evidence of infection of the communicable disease agent anti-HCV were shipped for further manufacture into injectable products. These units include [REDACTED], [REDACTED], [REDACTED], [REDACTED] and [REDACTED]. 21 CFR § 610.40(h).

Several deviations were identified in your handling of these units and the subsequent investigation and reporting of this incident.

- a) The units were recorded in the disposition log as being placed in a biohazard container on November 29, 2001. Our investigator was advised that recording the discarding of the units in the disposition log does not always happen concurrently with the actual discarding of the unit. This is a failure to maintain concurrent recordkeeping. 21 CFR § 606.160(a)(1).

- b) Your firm was advised in March 2002 by the consignee that "extra units" had been shipped. Your investigation into this incident was inadequate in that you did not identify additional unsuitable units shipped during the same time period until your consignee informed you of the shipment in June 2002 of another "extra unit." Further, on March 11, 2003, unsuitable units, as deemed by your firm ( [REDACTED] ), were inadvertently shipped. This is a failure to perform a thorough investigation into these deviations to prevent their recurrence. 21 CFR § 606.100(c).
  - c) Your firm failed to report the distribution of Normal Source Plasma units [REDACTED] and [REDACTED] as a deviation from current good manufacturing practices that may affect the safety, purity, or potency of that product, as required by biological product deviation reporting regulations, 21 CFR § 606.171(b)(1)(i).
2. The skin of the donor at the site of phlebotomy is not always prepared by a method that gives maximum assurance of a sterile container of Source Plasma. For example, the venipuncture site was not scrubbed for a total of [REDACTED] seconds as required by the method outlined in your firm's procedures for units [REDACTED] and [REDACTED] collected on March 11, 2003. 21 CFR § 640.64(e).
  3. A full explanation of a donor reaction, including measures taken to assist the donor and the outcome of the incident, is not always recorded on the donor's record. Four donor cards indicated donor reactions occurred, however, no additional information was present. These include units [REDACTED] and [REDACTED]. 21 CFR § 640.72(d).
  4. The Haemonetics PCS2 automated collection devices are not observed, standardized, and calibrated as prescribed in the Standard Operating Procedures Manual. 21 CFR § 606.60(a).
    - a) The Events Tracking Log for PCS2 96J061R/10 indicated that underdraws occurred on November 14, 2002, and November 16, 2002, and were the result of a machine malfunction, yet no corrective action or calibration occurred to correct the error.
    - b) The Events Tracking Log for PCS2 9SA020/05 indicated that an underdraw on November 16, 2002, was the result of a machine malfunction, yet no corrective action or calibration occurred to correct the error.
    - c) The Events Tracking Log for PCS2 96F233R indicated the machine was taken out of service between November 26, 2002, and November 30, 2002, yet there is no documentation recording why the machine was taken out of service, or what service was performed before placing the PCS2 back into service.

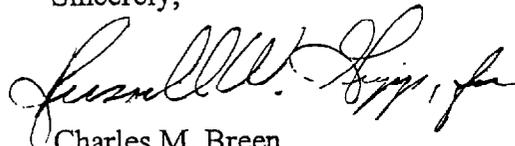
Barry Plost, Chief Executive Officer  
Biomat USA, Inc., Los Angeles, California  
Re: Warning Letter SEA 03-18  
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The above-identified deviations are not intended to be an all inclusive list of deficiencies at your facility. You are responsible for ensuring that your plasmapheresis center operates in compliance with the Act and the CGMP regulations for blood and blood components. We may take action without further notice if you do not promptly correct these deviations. Such action includes license suspension and/or revocation, seizure, and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. Include examples of any documentation such as retraining records, records of investigation, or other records demonstrating corrective action. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421, Attention: Lisa M. Althar, Compliance Officer.

Sincerely,



Charles M. Breen  
District Director

Enclosures:  
Form FDA 483

cc: Claus L. Winther, President/Authorized Official  
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