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

COPY

April 14, 1999

Telephone: 425-486-8788
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VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-14

Gary Crandall, Owner
Bio-Medics
111 N. Long Beach Blvd.
Compton, California 90221

WARNING LETTER

Dear Mr. Crandall:

During an inspection of Bio-Medics, at 48 East Main Street, Rexburg, Idaho on February 4 through 6, 1999, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to maintain and/or follow written standard operating procedures to include all steps to be followed in the collection, processing, storage, and distribution of blood and blood products [21 CFR 606.100(b)], in that:
 - a. Four donors had red blood cells reinfused after the seal was broken on the centrifuge bowl during the plasmapheresis procedure. Procedure 140.1 and the Manual indicate the contents of the centrifuge bowl cannot be considered safe for reinfusion after a centrifuge bowl failure occurs.
 - b. Three donors experienced two red blood cell losses within an eight-week period and they were not deferred per procedure 140.16. The donors were subsequently pheresed during the required eight-week deferral period.
 - c. Three donors with irregular pulse rates were allowed to donate on February 4 and 5, 1999, without having the procedure repeated as required in procedure 40.12, Pulse. Two donors with a distorted blood pressure signal were allowed to donate on February 4, 1999, without having the procedure repeated as required in procedure 40.11, Blood Pressure.

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Bio-Medics, Compton, California
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2. Failure to maintain complete and accurate records, [21 CFR 606.160(a)(1)] in that, the plasma weights required on the Plasma Donor List Shipping and Receiving Log are not maintained concurrently with the performance of the step. The plasma weights are first recorded on a paper towel and then later transferred to the Plasma Donor List Shipping and Receiving Log. When errors were made while transferring the data on February 4, 1999, the record with errors was discarded and a new record was started.

The above-identified deviations are not intended to be an all inclusive list of deficiencies at this facility. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations.

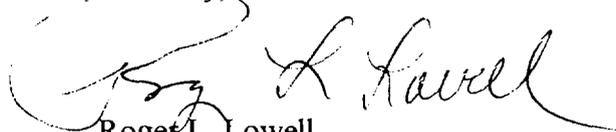
We received your letter dated February 24, 1999, addressed to Dolores Price, Investigator. Corrective actions addressed in that letter may be referenced in your response to this letter as appropriate. Whereas, your response to FDA 483 item 2 covers the in-service class held to retrain employees in responding to a broken centrifuge seal, it does not indicate if the applicable procedures were evaluated and revised to include discontinuing the plasmapheresis collection when the setup has been compromised. The procedure should also include directions on proper documentation of the incident.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. 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 violations and to prevent their recurrence. 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 directed to the Food and Drug Administration, Seattle District Office, Attention: Miriam Burbach, Compliance Officer, at the above mailing address.

Sincerely,



Roger L. Lowell
District Director

cc: Nikki J. Radford
Center Manager
Bio-Medics
48 East Main Street
Rexburg, Idaho 83440