



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

m4173n

Telephone: 425-486-8788  
FAX: 425-483-4996

September 12, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-95

James F. Crispen, M.D., Medical Director and Authorized Official  
Sera-Tec Biologicals Limited Partnership  
931 North Seventh Street  
Harrisburg, Pennsylvania 17102

WARNING LETTER

Dear Dr. Crispen:

We inspected your firm located at 2015 Eighth Avenue, Seattle, Washington, on August 1 through 4, and 7 through 9, 2000. During that inspection our investigators 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 remove donors from the plasma collection program until their plasma protein composition returned to the normal range established by the testing laboratory [21 CFR 640.65(b)(2)(i)] in that Donor [REDACTED] was permitted to donate Source Plasma on June 28, 2000, and Donor [REDACTED] was permitted to donate Source Plasma on June 29, 2000, following receipt of test results on June 13, 2000, indicating that both donors had abnormal plasma protein compositions.
2. Failure to process repeat donors as new donors when a four-month sample could not be obtained for a period exceeding six months [21 CFR 640.65(b)(1)(iii)] in that Donor [REDACTED] donated Source Plasma on March 29, 2000, and Donor [REDACTED] donated Source Plasma on July 11, 2000, without undergoing new donor physical examinations when more than six months had elapsed since their last four-month sample collection.
3. Failure to maintain and/or follow written standard operating procedures (SOPs) to include all steps to be followed in the collection, processing, storage, and distribution of blood and blood components [21 CFR 606.100(b)] in that the medical supervisor did not approve the plasmapheresis collection for the following donors when more than four months had elapsed since their last four-month sample collection:

Donor number:



Procedure:

May 4, 2000  
May 5, 2000  
May 6, 2000  
May 10, 2000  
May 10, 2000  
June 8, 2000 and June 10, 2000  
June 24, 2000 and June 27, 2000

4. Failure to limit plasmapheresis collections to no more than twice in a seven day period [21 CFR 640.65(b)(8)] in that Donor  donated Source Plasma on May 19, 2000, May 23, 2000, and May 25, 2000, and Donor  donated Source Plasma on June 21, 2000, June 23, 2000, and June 27, 2000. In addition, Donor  donated on the above three dates during a time period in which your firm also failed to defer this donor for a red blood cell loss.

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

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 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. Brzen  
District Director

James F. Crispen, M.D., Medical Director and Authorized Official  
Sera-Tec Biologicals Limited Partnership, Harrisburg, PA  
Re: Warning Letter SEA 00-95  
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cc: Mr. Joseph Rosen, President  
Sera-Tec Biologicals Limited Partnership  
223 North Center Drive  
North Brunswick, New Jersey 08902

Mr. Scott A. Blessum, Center Manager  
Sera-Tec Biologicals Limited Partnership  
2015 Eighth Avenue  
Seattle, Washington 98121