



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

75
M2503N

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

April 2, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James F. Crispen, M.D., Responsible Head
Sera-Tec Biologicals Limited Partnership
260 Reily Street
Harrisburg, Pennsylvania 17102

Dear Dr. Crispen:

During inspections of your facility, Sera-Tec Biologicals United Partnership, 5938 Baum Boulevard, Pittsburgh, Pennsylvania, ending January 25, 1999, and, March 22, 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 (SOP's) that include the steps to be followed in the collection, processing, storage, and distribution of blood and blood components [21 CFR § 606.100], for example:
 - a. Plasma unit #00127370, which tested HIV-1 antigen repeatedly reactive, indeterminate by neutralization, was collected at the above facility and released for manufacture into injectable product.
 - b. The above facility's look-back operations failed to identify Unit #97944850 as being collected from a donor who subsequently tested HIV-1 antigen repeatedly reactive. As a result the fractionator was not notified that this unit had been previously shipped for manufacture into injectable product.
 - c. Failure to document the required daily calibration and quality control for refractometer #4 from 3/19/98 through 4/1/98.
2. Failure of personnel to have a thorough understanding of the procedures or control operations they perform, and/or the necessary training or experience in their respective functions, [21 CFR § 606.20], in that,

Multiple personnel who reviewed the HIV-1 antigen test results for the above unit #00127370 (item 1.a.) were not aware of the requirement to destroy this product on the basis of these test results.

Page 2 - James F. Crispen, M.D.

3. Failure to maintain a complete and accurate record from which unsuitable donors may be identified so that products from such individuals will not be distributed [21 CFR § 606.160(e)], in that,

The above facility was notified that unit #00127370 was HIV-1 antigen repeatedly reactive, indeterminate by neutralization, on 6/8/98; however, the Donor Deferral Registry was not updated until 6/16/98. As a result this donor was accepted for donation and plasma units #01101270 and #01102895 were collected on 6/9/98 and 6/11/98 respectively.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. As top management it is your responsibility to assure that your establishment is in compliance with all requirements of Federal Regulations as well as all other requirements of the FD&C Act.

We are concerned that this and previous inspections of your plasmapheresis facility have revealed ongoing violations of Current Good Manufacturing Practice For Blood And Blood Components [21 CFR § 606] related to, the release of unsuitable units for manufacture into injectable product, inadequate blood product record review, failure of personnel to have a thorough understanding of procedures or control operations, and, personnel failing to follow Blood Bank Standard Operating Procedures (previous FDA-483's are attached).

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

We acknowledge the receipt of your letter of March 11, 1999, which proposes corrective actions to the Inspectional Observations noted on Form FDA-483 issued January 25, 1999; however, in view of your past violative history we are asking that you notify this office in writing within (15) working days of receipt of this letter of all specific actions that have been implemented to correct the noted violations. This should include verification of the training of personnel and an explanation with verification of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within (15) working days, state the reason for delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Philadelphia District Office, Room 900, U. S. Customhouse, 2nd and Chestnut Streets, Philadelphia, PA 19106, to the attention of William J. Forman, Compliance Officer.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District

Page 3 - James F. Crispen, M.D.

Attachments:

FDA-483, Inspectional Observations, dated, 1/25/99, 1/12/98, & 4/22/97.

cc: Joseph Rosen, President
Sera-Tec Biologicals Limited Partnership
223 North Center Drive
North Brunswick, New Jersey 08902

PDH Bureau of Laboratories
Blood Bank Division
Pickering Way & Welsh Pool Road
Lionville, Pennsylvania 19341