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Certified/Return Receipt Requested

October 9, 1998

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Richard E. Devoll, Managing
Director of Operations
Serologicals, Inc.
780 Park North Blvd., Suite #110
Clarkson, GA 30021

KAN #99-001

Dear Mr. Devoll:

During an inspection of Seramed BioCenter, located at 916 Nebraska Street, Sioux City, Iowa, on August 31 through September 4, 1998,, our investigator documented violations of Sections 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations, Parts 600-680. The deviations found include, but are not limited to, the following:

Failure to determine donor suitability on each day of plasmapheresis in that repeat donors are not being adequately screened for high risk behavior and signs and symptoms associated with AIDS [21 CFR 640.63(a)].

For example, Bayer Plasmapheresis Manual (BPM 201/REV- 4) 5.3.3 is not being adequately followed, in that repeat donors are not directed to read the "DO NOT DONATE PLASMA!" poster, yet they sign their medical history form that they have read and understood the poster.

On August 31, 2 out of 3 repeat donors were observed to not read the "DO NOT DONATE PLASMA!" poster even though the screener asked the question about reading and understanding it.

Bayer Plasmapheresis Manual (BPM 201/REV-4) 5.2.17 states in part "A DO NOT DONATE PLASMA! poster...is to be posted in the donor interview area for the donor's reference during questioning."

The above has a revision date of July 7, 1997. Information provided to this office by Bayer in July, 1997 indicates section 5.2.17 was to contain the following sentence: "**Ask the donor to read the poster and ensure that the donor has adequate time to do so.**" This has apparently been left out of Bayer's revision.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as Managing Director to assure that all of your establishments are in compliance with all requirements of the federal regulations. At the conclusion of the inspection Form FDA 483, Inspectional Observations, was issued to and discussed with Stephanie Stuart, Manager. A copy of this form is enclosed for your information.

We received and reviewed your letter dated September 11, 1998, concerning the Form FDA 483 observations, prior to the issuance of this letter.

Prompt action should be taken to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps, in addition to those covered in the letter, that are being 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 Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

Mary Wolske
W. Michael Rogers *for*
District Director
Kansas City District

Enclosure - Form FDA 483