



January 9, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2002-01

Claus L. Winther, President
SeraCare Acquisitions, Inc.
919 West Cucharras
Colorado Springs, CO 80905

Dear Mr. Winther:

Recently an inspection was made of your plasma donor facility located at 1301 SW Topeka Avenue, Suite 3, Topeka, Kansas. This inspection was conducted on November 27 through December 12, 2001, by a Food and Drug Administration Investigator from this office who documented deviations from Title 21, Code of Federal Regulations, Parts 600-680. These deviations cause the plasma products prepared at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act). The deviations found include, but are not limited to, the following:

Failure to assure that personnel responsible for product distribution had the necessary training and experience required to determine that the final product was acceptable [21 CFR 606.20(b)]. For example:

The center manager and assistant manager were involved with the improper release of units of plasma that were HCV reactive, and units of plasma collected from a donor known to have been incarcerated for greater than 72 hours. Both employees were involved with product distribution responsibilities before they had received supervisory certification, and with little experience in distribution operations. The assistant manager performed these duties prior to receiving related training.

Failure of employees to consistently follow Standard Operating Procedures (SOPs) pertaining to donor

suitability and plasma collection [21 CFR 606.100(b)]. Examples include:

SOP 60.7 (Handling Reactive Viral Marker Results) –

Donors with permanent or temporary deferrals are being allowed to donate.

Not always submitting the Look Back/Alert Notification within the two-day time limit after receipt of reaction information.

SOP 50.1 (Hypotensive/Vaso Vagal Reactions) –

The Medical Incident Report form (MIR) is not always completed according to the SOP. For instance no documentation of QA reviews on some forms, and a MIR not being prepared for almost three weeks after an incident of vaso vagal reaction.

SOP 20.8 (Hematocrit Determination) –

This SOP is not always followed with regard to the documentation of out-of-range readings.

Failure to consistently review and document investigations and corrective actions regarding errors found in records, prior to the release or distribution of plasma products. [21 CFR 606.100(c)].

Failure to submit reportable blood product deviations to the Food and Drug Administration within 45 days of discovery [21 CFR 600.14(a)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further manufacturing of your blood products.

We have received a letter dated January 4 from Mr. Charles Auger, Director of Quality, which is his response to the FDA 483 observations. Mr. Auger's letter was taken into account for the preparation of this Warning Letter. We will respond to Mr. Auger by a separate letter.

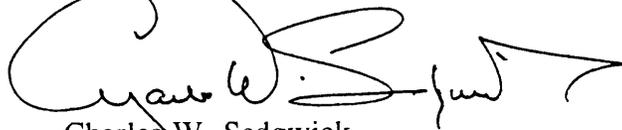
It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter, if Mr. Auger's letter should be considered as a response to this letter, or of other steps you are taking to correct the

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problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is fluid and cursive, with a large initial "C" and a long, sweeping tail.

Charles W. Sedgwick
District Director
Kansas City District

cc: Jamie R. Bolze
Center Manager
SeraCare Acquisitions, Inc.
1301 SW Topeka Ave., Suite 3
Topeka, KS 66612