



DEPARTMENT OF HEALTH & HUMAN SERVICES

117I-35
Public Health Service
Food and Drug Administration

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1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

SEP 22 2000

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

John Langstaff, Ph.D.
President and CEO
Cangene Corporation
104 Chancellor Matheson Road
Winnipeg, Manitoba
Canada R3T 5Y3

W/L 86-00

Dear Dr. Langstaff:

During an inspection of Serex International, Inc. (Serex) located in Van Nuys, CA conducted June 26 through 29 and July 5, 2000, our investigators documented violations of Title 21, Code of Federal Regulations (CFR), § 600 as follows:

Failure to ensure that personnel responsible for the collection, processing, compatibility, testing, storage, and distribution of blood or blood components have adequate training and/or experience to competently perform their assigned functions [21 CFR 606.20(b)]. For example, the employee identified as responsible for review of prior donations by a donor was unable to use the equipment required to perform the review.

Failure to maintain written procedures for all steps to be followed in the collection, processing, compatibility, testing, storage, and distribution blood or blood components [21 CFR 606.100(b)]. For example, your written procedures do not require review of prior donations by a donor to determine if they have been previously identified as unsuitable for use.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the federal regulations.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as license suspension and/or revocation, seizure and/or injunction.

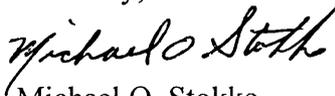
We acknowledge receipt of your response to the FDA-483, Inspectional Observations dated July 17, 2000, in which you commit to specific corrective actions. We are disappointed by our findings during this inspection regarding your implementation of previously promised corrective actions. In your response, you also committed to notify FDA when the above corrective actions have been completed and you have determined the facility is ready to resume operations. In addition to the above commitments, we request that you not resume distribution until after an acceptable FDA inspection is concluded.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the status of the specific steps you have committed to take to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within the time frames committed to in your response, state the reason for the delay and the time within which corrections will be completed.

Your written response should be directed to the Food and Drug Administration, Attention:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,



Michael O. Stokke
Acting District Director

cc: Michael G. Seifert
Center Director
Serex International, Inc.
14425 Sherman Way
Van Nuys, CA 91405