



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

**BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202**

30 May 1997

WARNING LETTER BUF 97-19

Martin Davidson, M.D.
Responsible Head
Champlain Valley Physicians Hospital Medical Center
75 Beekman Street
Plattsburgh, NY 12901

Dear Dr. Davidson:

Inspection of your blood bank facility at 75 Beekman Street, Plattsburgh, New York, was performed 5-21 May 1997 by Food and Drug Administration Investigators Richard W. Thornton and Denise L. Terzian.

The inspection revealed during the period 1/11/96 through 4/21/97 your facility shipped 66 units of unlicensed autologous blood, in interstate commerce, in violation of Section 351 of the Public Health Service Act [42 U.S.C. 262(a)].

The inspection also revealed blood and blood products manufactured by your hospital blood bank are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). They are adulterated because the controls used for their manufacture, processing, packing or holding are not in conformance with current good manufacturing practice regulations [Title 21, Code of Federal Regulations (21 CFR) Parts 600-680], as follows:

-Discrepant donor records were found in your database which relate whole blood unit numbers to incorrect donors [21 CFR 606.160(c)];

-Written labeling procedures are not adequate to assure autologous whole blood and allogeneic Fresh Frozen Plasma are properly labeled [21 CFR 606.100(b)(16)];



- Written standard operating procedures are inadequate because they do not identify the steps necessary to preclude shipment of non-licensed products in interstate commerce: they do not include procedures for correcting discrepant computerized donor records; they do not require the recording of critical processing steps for the manufacture of Platelets and Fresh Frozen Plasma; they do not require a determination of mobile site suitability prior to use; they do not identify systems in place for review of irradiation processes and procedures prior to release of irradiated products; and they do not identify procedures for verifying destruction of blood products [21 CFR 606.100(b) and (c)];

-Documentation is not maintained for significant processing steps in the manufacture of Fresh Frozen Plasma or Platelets; for actual incubation times used in viral marker testing; and for review of all records generated subsequent to destruction of blood products. In addition, viral marker test strips are not initialed or dated by the analyst [21 CFR 606.100(c) & 606.160(a)];

-Errors and accidents occurring in the processing of blood products released by your facility, which may effect their purity, safety and/or potency, have not been reported to FDA's Center for Biologics Evaluation and Research [21 CFR 600.14];

-Thorough investigations have not been made, and appropriate corrections have not been taken and documented, for errors and accidents occurring in the manufacture of blood products which may effect their safety, purity or potency [21 CFR 606.100(c)];

-Failure to follow written procedures for investigating and documenting lookbacks and post donation reports [21 CFR 606.100(b)&(c)];

-Periodic reconciliation is not performed for blood products manufactured/issued and/or destroyed by your facility [21 CFR 606.100(c)];

-Records are not maintained to demonstrate testing solutions and venipuncture site preparation materials, used in the collection of whole blood, are within expiration dates; there are no records to indicate preventative maintenance checks have been performed, in accordance with the manufacturer's instructions, for manometers used in the determination of donor suitability [21 CFR 606.160(b)].

You should take prompt action to correct these violations and establish procedures whereby such violations will not recur. Failure to achieve prompt corrections may result in regulatory action - without further notice. This may include license suspension and/or revocation, seizure and/or injunction.

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Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the award of contracts. Blood products are considered drugs within the meaning of the Act. By copy of this letter, we are specifically advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of State or Federal law.

Please notify this office, in writing, within fifteen (15) days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Team Leader, at the above address.

Sincerely,



Edward W. Thomas
Acting District Director

cc: Kevin Carroll, President
Champlain Valley Physicians Hospital Medical Center
75 Beckman Street
Plattsburgh, NY 12901

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