



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Refer to: CFN 1176243

Food and Drug Administration  
Baltimore District Office  
Central Region  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-3396  
FAX: (410) 962-2307

November 5, 1999

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Robert E. Carden, President  
Virginia Blood Services, Inc.  
2201 Westwood Avenue  
Richmond, Virginia 23230

Dear Mr. Carden:

During a Food and Drug Administration (FDA) inspection of your blood bank at 2201 Westwood Avenue, Richmond, Virginia, conducted September 30 through October 26, 1999, our investigators documented deviations from the Current Good Manufacturing Practice Regulations, Title 21, Code of Federal Regulations (21 CFR), Parts 600-680. These deviations cause your blood products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

1. Failure to maintain complete and accurate records of component preparation per 21 CFR 606.160, as follows:
  - No records could be located of the irradiation of approximately [REDACTED] units of blood products from December 8 through December 24, 1998;
  - The "Irradiation Logs" for 9/6/99 indicated that two batches of blood products were irradiated during the same time period;
  - Red Blood Cell (RBC) units KE82562 and KQ42621 were documented as being shipped at 16:35 on 10/23/98 and irradiated between 17:15 and 17:30 on that same date;
  - RBC unit KF24867 was documented as being modified to "Irradiated" in the computer at 17:24 on 10/29/98 during the time that the unit was in the irradiator; and
  - Platelet units KJ39522 and KE82299 were documented as being modified to "Irradiated" in the computer at 17:00 on 10/19/98, prior to the irradiation cycle, which ran between 17:00 and 17:20 on 10/19/98.
2. Failure to follow standard operating procedures (SOP) per 21 CFR 606.100, as follows:

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- There was no documentation of a computer override that occurred during a mobile blood drive on 8/31/99 regarding incorrect unit numbers on the "Blood Donor Registration Form," per SOP #02-102.
  - SOP #08-310, "Irradiation of Blood and Blood Components," specifies that units of red blood cells (RBC) can not be out of refrigerated storage longer than 30 minutes. Your records indicate numerous instances where RBC units were out of refrigeration storage for periods in excess of 30 minutes. In one instance, RBC unit T 02121 was out of refrigerated storage from 1:30 a.m. to 6:20 a.m. on 9/16/99, a total of 4 hours and 50 minutes; and
  - An audit of the "Irradiation Logs" was not performed from 10/1/98 through 10/1/99, as required by SOP #01-210.
3. Failure to have or follow a system that would prevent the issuance of any products not suitable for use, in that despite supervisory review, the "Irradiation Logs" for the periods of 10/1/98 through 12/31/98 and 9/1/99 through 9/30/99 contained deviations such as those in Item 2 above. [21 CFR 606.100]
  4. Supervisory review of the irradiation records was inadequate, in that the review failed to identify numerous incomplete or inaccurate component preparation records such as those identified in Item 1 above. [21 CFR 606]

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

You should take prompt action to correct the violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at 804-379-1627, ext. 14.

Sincerely,

  
Marc J. Balzarini  
Acting District Director