



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Refer to: CFN/FEI 11247532

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

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01-BLT-37

July 31, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Christopher P. Healy, President
American Blood Resources Association
147 Old Solomon's Road, Suite 100
Annapolis, Maryland 21401

Dear Mr. Healy:

During an inspection of your facility located in Annapolis, Maryland, on June 18 through 22, 2001, Food and Drug Administration (FDA) investigators determined that you manufacture and distribute, Blood Bank Deferral Software. This software is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). The device is considered adulterated within the meaning of section 501 (h) of the Act, in that the methods used in, or the facilities or controls used in the manufacture, processing, packaging, storage, or distribution of this software are not in conformance with the Quality System Regulation for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to document and validate design changes in that the National Donor Deferral Registry (NDDR) software was changed with regard to year 2000 update, modification of program files [REDACTED] and [REDACTED], without documenting the design changes, testing, validation, and verification as required by standard operating procedures (SOPs) (21 CFR 820.30(i)).
- Failure to maintain a complete Device Master Record (DMR). For example, the DMR lacked complete specifications for software installed on the host server and deferral record activity codes (21 CFR 820.181).
- Failure to establish and maintain adequate document change controls in that the business practice was changed regarding the use of computer generated [REDACTED] as opposed to the use of [REDACTED] numbers, for donor identification. The NDDR user manuals and design specifications were not changed to reflect this new practice. Also, approval of standard operating procedures was not documented in that the procedures lacked signatures of the individuals approving the documents and/or dates of approval. For example, SOP 33.003, "User Record Maintenance" and SOP 33.004, "Monthly Activity Report," were not signed as being approved (21 CFR 820.40 (b)).

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- Failure to follow SOPs with regard to the evaluation and documentation of complaints and inquiries. For example, Contact Management Forms were not fully completed. The forms fail to document whether the contacts numbered as "Inquiries" had been fully evaluated as to whether they were MDR reportable, an inquiry, a complaint, or whether there was an investigation or any conclusion or follow-up (21 CFR 820.198).
- Failure to conduct and document quality audits to assure the quality system is in compliance with quality system requirements (21 CFR 820.22) and to document the evaluation of contractors (21 CFR 820.50(a)). For example, there was no documentation available to show that either internal quality audits or an evaluation of the contract software developer had ever been performed.

We acknowledge receipt of your letter dated July 10, 2001, which responds to the Form FDA 483 issued at the close of the inspection. Your letter will be made part of the official file. Your responses are under review and will be addressed under separate cover.

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. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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.

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Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller may be reached at (703) 235-8440, extension 504.

Sincerely,

A handwritten signature in black ink, appearing to read 'LB', with a stylized flourish extending to the right.

Lee Bowers

Director, Baltimore District