



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

407
7/27/97
RB/7/18/97

Certified/Return Receipt Requested

July 15, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

WARNING LETTER

Ms. Jane A. Mackey, President and CEO
Responsible Head
Topeka Blood Bank, Inc.
800 SW Lane
Topeka, Kansas 66606

Ref.# - KAN-97-020

Dear Ms. Mackey:

During an inspection of your blood bank facility located at the above address, conducted on May 15 through June 16, 1997, Food and Drug Administration Investigators from this office documented violations of Sections 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act, and Title 21, Code of Federal Regulations, Parts 600-680. The deviations found include, but are not limited to, the following:

Failure to follow test kit manufacturer's instructions in the performance of certain laboratory tests [21 CFR 606.65(e)]. For example:

1. On 1-22-97 Unit K07883 tested initially reactive for Hepatitis (HBsAg), yet subsequent testing in duplicate was not performed.
2. In at least eight instances since May, 1996, you have not adequately performed EIA viral marker testing in that when aberrant control values should have required invalidation of the run, the initial results were re-read instead of having been invalidated and re-tested.

Failure to follow certain Standard Operating Procedures (SOP's), and failure to have a written SOP for use with viral marker assay results [21 CFR 606.100(b)]. For example:

SOP's Not Followed

DISTRIBUTION:

Orig.: Addressee

bcc: LF; FF (1971534); HFA-224; HFM-610; HFI-35/DIB(via FOI);
HFC-210; GDD; WMR; HFR-SW400 (Breen); KDHE (Posic); IBRF;
CRP:ak

1. SOP E.017, [REDACTED], for 1) not performing subsequent testing in duplicate on a unit found initially reactive, and 2) re-reading an initial HBsAg test run when it should have been invalidated and retested based on aberrant control values.
2. SOP E.041, [REDACTED] and SOP E.009, HIV-1 p24 Antigen ELISA Test, for re-reading initial test runs when they should have been invalidated and retested based on aberrant control values.
3. Manufacturer's instructions (SOP) for validation of the [REDACTED] upgrade, in that print screens were not always done for various test scenarios.

Lack of SOP

There is no SOP to address the invalidation/re-read of viral marker assay results which are used for the screening of donors.

Failure to provide supporting documentation to explain the reasons why at least 10% of each viral marker assay performed since May, 1996, was re-read [21 CFR 606.160(a)(1) and (b)(2)(i)].

Failure of SOP A.004, Medical History Questions, to include a deferral for donors who work in areas endemic for Hepatitis, of at least 12 months after termination of employment in such areas [21 CFR 640.3(c)(2)].

The above listed violations are not intended to be an all-inclusive list of the deficiencies which may be present at your facility. At the conclusion of the inspection Form FDA 483, Inspectional Observations, was issued to and discussed with you. As Responsible Head it is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

We have received and reviewed your letter dated June 24, 1997, which is a response to the Form FDA 483 observations. The letter was reviewed prior to the issuance of this letter. It appears from the letter that proper steps are being taken to correct the noted deviations.

Page 3
July 15, 1997
Topeka Blood Bank, Inc.

Prompt action should be taken to correct the violations. Failure to promptly correct the violations may result in regulatory action without further notice. Such actions may include license suspension and/or revocation, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, to inform us if the June 24 letter will suffice as your response to this letter, or you may expand on that letter with additional information concerning corrections being made. 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.

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

Sincerely,

W. Michael Rogers
District Director
Kansas City District