

HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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Refer to:

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

April 17, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas S. Kluge, Associate Administrator
Halifax Regional Hospital
2204 Wilborne Avenue
South Boston, Virginia 24592

Dear Mr. Kluge:

During a Food and Drug Administration (FDA) inspection of your hospital blood bank located in South Boston, Virginia, on March 25, 1997, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680, as follows:

1. Failure to maintain complete and accurate records of the storage, distribution, and disposition of each unit of blood and blood components [21 CFR 606.160(d)(3)(I)].
For example:
 - a. Four expired units of Fresh Frozen Plasma [REDACTED] and [REDACTED] could not be accounted for in the disposition log or found in the blood component freezer.
 - b. White-out was used to make corrections and/or changes to pages 12 and 44 of the blood disposition log.
 - c. No disposition record is maintained of the recovered plasma's destruction.
2. Failure to maintain adequate written standard operating procedures describing the method(s) of correcting records and documents [21 CFR 606.100(b)].

The above identified deviations 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 requirements of the federal regulations.

Mr. Thomas S. Kluge

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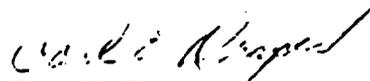
April 17, 1997

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such action includes seizure and/or injunction.

You should 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 and to prevent their recurrence. 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 response should be sent 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.

Sincerely,



Carl E. Draper
Acting Director, Baltimore District