

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

HFI-35 2/12/98  
D1359B

Refer to: CFN 1177846

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

January 16, 1998

**WARNING LETTER**

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

Alice L. Werner, M.D., Medical Director  
Children's Hospital of the King's Daughters  
601 Children's Lane  
Norfolk, Virginia 23507

Dear Dr. Werner:

During a Food and Drug Administration (FDA) inspection of your hospital blood bank located in Norfolk, Virginia on December 17 and 23, 1997, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 606, as follows:

1. Failure to follow physician's orders to irradiate 7 units of blood products as required by your standard operating procedures, and to document such in your daily irradiation records.
2. Failure to maintain complete and accurate records of the irradiation of blood products.
3. Failure to maintain complete and adequate written standard operating procedures describing the irradiation of blood products.

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.

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

Alice L. Werner, M.D.

Page 2

January 16, 1998

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. Mr. MacIntire can be reached at (804) 379-1627, Ext. 14.

Sincerely,

A handwritten signature in cursive script, appearing to read "Elaine Knowles Cole".

Elaine Knowles Cole  
Director, Baltimore District