

5/28/98



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
New York District Office

d18126

Telephone: (718) 340-7000 [ext. 5301]

WARNING LETTER

May 19, 1998

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Dr. George Pringle
Clinical Laboratory Administrator
Brookdale Hospital Medical Center
1275 Linden Boulevard
Brooklyn, New York 11212

Ref: 29-NYK-98

Dear Dr. Pringle:

During an inspection of your blood bank, conducted between March 30 and April 20, 1998, located at 1275 Linden Boulevard, Brooklyn, NY, 11212, 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 through 680 as follows:

1. Failure to restrict use of blood and blood components which were found to be reactive when tested for the Hepatitis B surface Antigen (HBsAg) [21 CFR 610.40(d)] in that blood and blood components (red blood cells and plasma) from two donations which tested reactive for HBsAg were released for allogenic transfusion. Two of the blood components were transfused.
2. Failure to maintain a record from which unsuitable donors may be identified so that products from such individuals will not be distributed [21 CFR 606.160(e)] in that the donor of unit 17342 (which tested repeatedly reactive for antibody to Hepatitis C) and the donor of unit 17601 (which tested repeatedly reactive for antibody to Hepatitis B Core Antigen) were not entered into the deferral system.
3. Failure to calibrate equipment [21 CFR 606.60(b)] in that the temperature calibration of the [redacted] refrigerated centrifuge used for component preparation has not been performed since installation of the unit in September, 1997.
4. Failure to maintain complete written Standard Operating Procedures (SOPs) for the criteria used for the interpretation of viral testing results, for completion of the donor log book

containing results and interpretation for individual units and for changes made in the donor log book.

5. Failure to maintain a record. For example :

a) The freeze/preparation time for approximately 20 of 167 units of Fresh Frozen Plasma prepared between January 1997 and March 1998 [21 CFR 606.160(b)(2)(ii)].

b) The return time for units of blood that were not used within the thirty minute time frames as specified in your Standard Operating Procedures into the Issue book. Some of these units of blood were used for transfusions after thirty minutes [21 CFR 606.100(b)(12)].

6. Failure to use reagents in the manner consistent with instructions provided by the manufacturer [21 CFR 606.65(e)] in that, the Reagent Quality Control media lots used in the daily reagent Quality Control were used beyond their expiration dates on the following days: 1/30-2/1/97, 3/27-29/97, 5/21-24/97, 6/19-21/97, 10/9-11/97, 11/6-8/97, 12/4-12/6/97, 1/29-31/98, and 2/26-28/98.

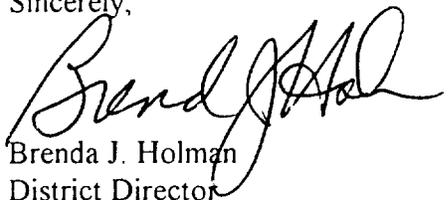
The above identified deviations are not intended to be an all inclusive lists of deficiencies at your facility. It is your responsibility as Clinical Laboratory Administrator to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by this Agency without further notice. Such action includes, a seizure and/or injunction.

Please notify this office in writing, within fifteen (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 fifteen (15) working days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U. S. Food and Drug Administration, New York District Office, 850 Third Avenue, Brooklyn, NY, 11232, attention: Anita Fenty, Compliance Officer.

Sincerely,



Brenda J. Holman
District Director

Brookdale Hospital BB
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cc: Dr. William Steier
Blood Bank Medical Director
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Brooklyn, New York 11212

cc: Jeanne Linden, MD
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