



G-4157J

Food and Drug Administration  
Baltimore District Office  
Central Region  
6000 Metro Drive, Suite 101  
Baltimore, MD 21215  
Telephone: (410) 779-5454  
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03 BLT-23

July 25, 2003

**WARNING LETTER**

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

Maurice B. Furlong, Jr., M.D.  
Chairman  
Department of Pathology  
Mercy Medical Center  
301 St. Paul Place  
Baltimore, Maryland 21202

Dear Dr. Furlong:

The Food and Drug Administration (FDA) conducted an inspection of your unlicensed registered blood bank facility located at 301 St. Paul Place, Baltimore, Maryland, on April 15-17, 21-22, 28, 2003. The inspection revealed numerous deviations from the current Good Manufacturing Practice (cGMP) regulations, Title 21, Code of Federal Regulations (CFR), Parts 211 and 606. These deviations cause your blood products to be adulterated under Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and your facility to be in violation of regulations promulgated pursuant to Section 361 of the Public Health Service Act. The investigator issued a Form FDA-483 to you at the conclusion of the inspection that listed the following deviations:

1. Failure to report cGMP deviations to FDA, including:
  - A unit of Fresh Frozen Plasma was labeled with the incorrect requisition number and distributed ([REDACTED]);
  - Pooled platelets were sent to the hospital floor without expiration date ([REDACTED]);
  - Two units of blood product were distributed with incorrect expiration dates ([REDACTED]).

[21 CFR 606.171(b)]

2. Failure to check the accuracy of input to and output from your computer or related system of formulas or other records or data. For example, the [REDACTED] which was put into use in November 2002, has not been validated. The standard operating procedure (SOP) entitled "[REDACTED]" outlined the steps to be followed in the validation of the blood bank computer system, however, numerous validation records and forms pertaining to the validation of the computer system were incomplete and/or did not note the

signatures of personnel who had performed or reviewed the validation. [21 CFR 211.68(b) and 606.100(b)]

3. Failure to follow written standard operating procedures in the collection, processing, compatibility testing, storage, and distribution of blood and blood components [21 CFR 211.100(b) and 21 CFR 606.100(b)], including:
  - a. The SOP entitled "[REDACTED]" was not followed. For example:
    - i. Approximately 102 of 196 Blood Bank Error Reports for 2001 and 157 of 250 Blood Bank Error Reports for 2002 had no documentation of review by the blood bank medical director, and, if necessary, by the chairman of the department of pathology as required by the SOP. In several incidences, employee [REDACTED] performed and documented the error or task and then signed as the supervisory reviewer.
    - ii. There was no documentation of the corrective actions that were implemented for approximately 265 out of 556 Blood Bank Error Reports, from March 2001 to the present, as required by the SOP.
  - b. There was no documentation indicating that FDA reportable events documented on Blood Bank Error Reports dated July 9, 2001, January 9, 2002, and May 23, 2002, were submitted to FDA as required by SOP entitled "[REDACTED]"
4. Failure to maintain an adequate number of trained and experienced personnel for the processing, compatibility testing, storage, and distribution of blood or blood components. For example, employee [REDACTED] who was responsible for completing validation of the [REDACTED] software, was also responsible for Quality Assurance, supervisory and administrative duties, training of personnel, tissue bank duties, and SOP development, in addition to performing approximately 80% of the laboratory workload (i.e., group and type, antibody screening, and compatibility testing of patient specimens). Additionally, the facility failed to train the aforementioned employee to perform validation of the [REDACTED] blood bank software [REDACTED] [21 CFR 606.20(b)]

The conditions described above are not intended to be an all-inclusive list of deficiencies at your blood bank facility. It is your responsibility to ensure that your blood bank facility is in compliance with all applicable requirements of the FDCA, PHSA, and their regulations including 21 CFR Parts 211 and 606.

You should take prompt action to correct these deviations. Failure to correct these deviations promptly may result in regulatory or legal action by FDA without further notice. Such action may include seizure and/or injunction.

We acknowledge receipt of your letter dated June 14, 2003, in response to the Form FDA-483 that was issued to you at the conclusion of the inspection of your facility. We have completed our review of your response and have determined that your response is inadequate to address all of the violations that FDA

documented at your facility. Our evaluation of your response follows and is numbered or labeled to correspond to the items as they appeared on the Form FDA-483 and in your response:

1. In your response, you stated that "Input and output from the computer were checked at the time of the upgrade. Paper work is being organized and labeled for documentation." However, during the inspection of your facility, you could not provide the investigator with adequate documentation supporting the validation of the [REDACTED]. Please provide detailed information supporting the validation of the [REDACTED].
2. In your response, you stated that "This revised SOP is being followed while completing the validation of [REDACTED]." Please provide the revised SOP for the validation of the [REDACTED].

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of any additional steps you have taken to correct the noted deviations and to prevent their recurrence. Your response should include examples of documentation showing that corrections have been achieved. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Vinetta Howard-King, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21228. If you have any questions, please do not hesitate to contact Ms. Howard-King at (410) 779-5454, extension 413.

Sincerely,



Lee Bowers  
Director, Baltimore District