



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 1171573

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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-14

May 30, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ronald R. Peterson, President
Johns Hopkins Hospital and Health Care Systems
600 N. Wolf Street
Baltimore, Maryland 21287

Dear Mr. Peterson,

The Food and Drug Administration (FDA) conducted an inspection of your blood bank facility located at 600 N. Wolf Street, Baltimore, Maryland, on February 3-6, 10, and 25, 2003. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (CFR), Parts 210, 211 and 606. These deviations cause your facility to be in violation of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The deviations observed included:

- Failure to observe, standardize, and calibrate equipment on a regularly scheduled basis to assure that it will perform in the manner for which it as designed, in that incubation time and temperature, agitation speed, and time for the [REDACTED] and [REDACTED], and the [REDACTED] which are components of the [REDACTED] have not been qualified. [21 CFR 211.68 and 606.60(a)]
- Failure to perform a thorough investigation and make record of the conclusions and follow-up of an unexplained discrepancy. Specifically, quality control investigations of discrepancies associated with the [REDACTED] system did not determine the cause of the discrepancies and no corrective actions were implemented to prevent recurrence. [21 CFR 606.100(c)]
- Failure to maintain written standard operating procedures (SOPs) including all steps to be followed in the compatibility testing of blood and blood components for homologous transfusion. Specifically, your blood bank lacks written SOPs for steps taken when the [REDACTED] system produces results that are inconsistent with patient history; and when the [REDACTED] system is unable to interpret antibody screening results. [21 CFR 606.100(b)(8)]

- Failure to submit a biological product deviation report. Specifically, blood product deviations documented on "██████████ Report Forms" were not reported to FDA as required. [21 CFR 606.171]

The above deficiencies 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 21 CFR Parts 210-211, Parts 600-680, and the Act.

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

We have received and reviewed your letter, dated April 16, 2003, regarding the FDA-483 issued at the conclusion of the February 2003 inspection. Our evaluation of your response follows, and is numbered to correspond to the items listed on the Form 483:

Observation 1: The response is inadequate, in that the "validation" data lacks specific details regarding the steps taken to qualify the equipment. For example, your response indicated that the incubation of the ██████████ instruments was performed for ██████████ minutes. However, there was no data or information regarding the assessment of the incubation temperature for the intended use of the equipment. Additionally, how were the times for the incubator assessed? Also, your response noted "target" and "actual" times for the incubator and ██████████ shaker. However, there was no indication as to how the measurements were taken.

Observation 2: The response is inadequate. While your firm implemented immediate corrective action to address the problems in your manufacturing procedures, you did not address your failure to thoroughly investigate unexplained discrepancies, including follow-up and conclusions.

Observation 3: The response appears to be adequate.

Observation 4: The response appears to be adequate.

Observation 5: While your firm promised to submit biological product deviation reports to FDA, there was no indication of the corrective measures implemented, if any, to keep the problem from recurring.

We request that you 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 deviations and to prevent their recurrence. Your response should include examples of documentation showing that corrections have been achieved. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

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May 30, 2003

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,

A handwritten signature in black ink, appearing to read 'L. Bowers', with a stylized flourish extending to the right.

Lee Bowers
Director, Baltimore District