



August 8, 2003

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER
Ref. KAN 2003-11

Mr. Peter E. Makowski
President & Chief Executive Officer
Mercy Medical Center - Sioux City
801 5th Street
Sioux City, IA 51101

Dear Mr. Makowski:

During an inspection of your blood bank operation located at the above address on June 30 – July 2, an investigator from this office 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:

Failure to maintain complete records of an adverse reaction arising as a result of transfusion. [21 CFR 606.170(a)] Specifically, the Transfusion Reaction Investigation involving Irradiated Random Platelets from pool PL 0613 does not include patient disposition information.

Failure to report the fatal transfusion reaction involving Irradiated Random Platelets from pool PL 0613 to FDA's Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, in a timely manner. [21 CFR 606.170(b)]

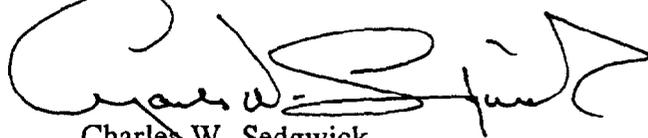
The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

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

Mr. Peter E. Makowski
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Please 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 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 reply should be sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is stylized with large loops and a long horizontal stroke.

Charles W. Sedgwick
District Director
Kansas City District