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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

August 17, 2001

WARNING LETTER
CHI-43-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Phillip Dionne, President and CEO
Holy Cross Hospital
2701 West 68th Street
Chicago, IL 60629

Dear Mr. Dionne:

During an inspection of your unlicensed blood bank, between April 4 and April 6, 2001, Investigator Mark A. Kaspar 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. At the conclusion of the inspection, a Form FDA 483, Inspectional Observations (FDA 483), was issued and discussed with Dr. P. Shah, Medical Director of the Clinical Laboratory and Pathological Services. A copy of the FDA 483 is enclosed for your information. The violation reported is as follows:

Failure to investigate adverse reactions and maintain appropriate records [21 CFR 606.170(a)] in that:

- Our investigator examined records covering suspected adverse transfusion reactions from January 2000 through April 4, 2001, and of the 46 suspected adverse transfusion reactions reported, no investigations were initiated for 20 of the suspect transfusion reactions.

The above violation is not intended to be an all-inclusive description of deficiencies at your facility. It is your responsibility as President and CEO to assure your establishment is in compliance with all requirements of the regulations.

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

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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 or plan to take 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 the attention of George F. Bailey, Compliance Officer, at the above listed address.

Sincerely,

\s\
Raymond V. Mlecko
District Director