



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

September 27, 2001

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

g1832d

WARNING LETTER
CHI-56-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jay F. Schamberg, M.D.
General Manager of ACL
Christ Hospital
4440 West 95th Street
Oak Lawn, IL 60453

Dear Dr. Schamberg:

During an inspection of your unlicensed blood bank, conducted on July 26, 30 and August 1, 2001, 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, Parts 211 and 600-680, as follows:

Failure to conduct validation studies on the "██████████" software used to control irradiation dose calculation, irradiation timing, product expiration dating and electronic data reporting [21 CFR 211.100(b)].

Failure to establish written procedures that include all steps to be followed in the collection, processing, compatibility testing, storage and distribution of blood [21 CFR 606.100(b)]. For example, no written procedures exist that define the ██████████ Software Donor Module that has been in use at your facility since November 1998.

Failure to review all records pertinent to the lot or unit prior to release or distribution of the product [21 CFR 606.100(c)]. For example, the inspection revealed that your firm's procedures do not require processing records to be reviewed to assure products meet their pre-defined specifications.

Failure to maintain adequate donor record files [21 CFR 606.160(b)]. For example, the inspection revealed that of ██████ donor records reviewed by our investigator, record for ██████ donors contained insufficient information to determine if the donors had traveled to areas at risk for malaria. Products have been collected from these four donors and Red Blood Cells were issued for transfusion.

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The above listed violations and the FDA-483, Inspectional Observations, issued and discussed with you at the conclusion of the inspection, is 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 violations may result in regulatory action without further notice, such as seizure and/or injunction.

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