



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35 ^{new} 4/17/97 S/G
Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

M 8274

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

FLA-97-46

April 16, 1997

Dr. Alberto Rey, Director
Mercy Hospital Blood Bank
3663 S. Miami Avenue, 3rd Floor
Miami, Florida 33133

Dear Dr. Rey:

Inspection of your unlicensed hospital blood bank on April 2-3, 1997, by FDA Investigator, Holly S. McNair, revealed serious violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented that the methods used in, or the facilities or controls used for, the manufacture, processing, packing, holding or distribution of blood and blood products are not in conformity with the Current Good Manufacturing Practice (CGMP) regulations prescribed in Title 21 Code of Federal Regulations, Part 606 (21 CFR 606).

Inspection revealed that blood product disposition records prior to November of 1996 are not available. According to your blood bank supervisor, the missing disposition records were transferred to a computer system and were subsequently "lost" by that system. Your supervisor stated the computer system has not been validated and is being used only for "practice." Your supervisor also stated the blood bank had written back-up records for the data in the computer system. However, written disposition records could not be produced during the inspection for review.

Inspection also revealed that established written procedures for storage temperature controls, equipment maintenance, and record keeping are not being followed. The investigator documented numerous instances where temperature recorder charts on storage refrigerators exceeded specifications, whereas daily temperature logs show that refrigerator temperatures were within specified limits. Your supervisor stated that one temperature recorder is broken and personnel are allowed to bend the arm/pin back into place in an attempt to maintain the device. No documentation is available to show calibration and maintenance of the recording thermometers.

The investigator also documented that quality control checks on other laboratory equipment are not being performed in accordance with established written procedures. Numerous records reviewed during the inspection contained illegible corrections and there is no documentation that these records were reviewed by a supervisor. There is no assurance that your blood bank personnel have been properly trained to perform their assigned duties.

In addition, some written procedures established in 1981 have not been updated and were last reviewed by a supervisor in 1994. Two procedures entitled "File XI.1," one dated September 1981, and the other dated May 1991, are both currently in use and provide different instructions for the same procedures. Written procedures also contain numerous hand written changes and are no longer clear and concise.

We note that several of the above deficiencies have been repeatedly listed on Inspectional Observations (FDA Form 483's) issued to your blood bank at the conclusions of FDA inspections on April 27, 1993, October 28, 1993, and June 16, 1996. On each occasion, management promised corrective action. This inspection reveals that adequate corrective action has not been implemented or maintained.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your blood bank is in compliance with the Act and the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay, and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,


Douglas D. Tolen
Director, Florida District