



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

margin

Telephone (973) 526-6009

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

September 14, 1999

WARNING LETTER

Dr. Frank Gradone, President/CEO
The Blood Center of New Jersey
45 South Grove Street
East Orange, New Jersey 07018

File No: 99-NWJ-36

Dear Dr. Gradone:

During an inspection of The Blood Center of New Jersey, located at 45 South Grove Street in East Orange, New Jersey, from June 7 - 22, 1999, Investigators from the New Jersey District Office documented violations of Section 501 (a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Parts 600-680, as they relate to the collecting, processing and testing of blood and blood components. These deviations were cited on an FDA483 List of Inspectional Observations, issued at the close of the inspection.

The significant deviations are as follows:

1. Failure to follow SOP E2.007 Invalid Runs, in that all trays in the test run were invalidated when only the single tray which exceeded the times set by the manufacture for incubation of the *o*-phenylindiamine-2HCL (OPD) solution should have been invalidated. This resulted in inadequate testing of units.
 - a. For example, the initial test result for unit 5663750 for anti-HBc performed on 2/26/99 was reactive however, the unit was not retested in duplicate.
 - b. Review of test records by personnel failed to detect the deviation from procedures and as a result, products of unit 5663750 were released for distribution without appropriate retests being performed.

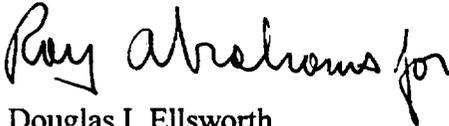
2. Incomplete validation of equipment used in testing and transporting blood products. For example:
 - Coolers used to transport unprocessed blood units from fixed sites were not validated to demonstrate that they are capable of maintaining units at required temperatures. Representative units arrive at the processing center within the established range of 1-30° C, however, there is no data to support this temperature range.
3. Failure to promptly report to the Center for Biologics Evaluation and Research (CBER), as an Error & Accident, the use of outdated anti-A and anti-B reagents for laboratory testing in that on 3/1/99 it was discovered that ABO typing of blood and blood components was being performed with expired anti-A and anti-B reagents, since 2/3/99 and 2/20/99, respectively. The error was reviewed by the Medical Director on 3/8/99, however, no Error & Accident Report was submitted to CBER subsequent to the review.
4. Failure to follow SOP N2.003 Incident /Error Reporting, in that all of the events related to Incident Reports 98-103, 98-104 and 98-107, were not adequately documented and appropriate corrective actions were not implemented.
5. There is no routine review of donor registration activities to ensure accuracy of donor information into the computer system. For example, a first time donor was incorrectly entered and deferred for repeat reactive HCV test results under a different name.

The above 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 federal regulations, with regard to blood collection, processing, testing and distribution. You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction, license suspension and/or revocation.

We have received your written response to the FDA483 List of Inspectional Observations, dated July 19, 1999. Your response contains appropriate immediate and long-term correction actions. It should be noted that the observations made, especially in regard to invalid test runs, validation issues and failure to follow SOPs, demonstrate serious deficiencies in your Quality Assurance system. Your further response should include specific steps you plan to implement to improve QA oversight.

Please notify this office in writing within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including supporting documentation. Your further response should be sent to the Food & Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



Douglas I. Ellsworth
District Director
New Jersey District

Cc: Ms. Tina Ilao, Responsible Head
The Blood Center of New Jersey
45 South Grove Street
East Orange, New Jersey 07018

RELEASE

REVIEWED BY Mercedes Mota 9/17/99
C.O. DATE

**Bcc: HFR-CE340 (DCB/MBM/JKT/WL File)
HFR-CE350 (DIB/Gp4-SCSO/Cabrera/VRP-Schofield/NBRP-Gubernot)
HFM-610 (CBER, Attn: Stephany Kersten)
HFA-224
HFC-210 (Division of Compliance Policy)
HFI-35 (FOI - stamped & purged copy)
EF (The Blood Center of New Jersey, East Orange, NJ)**

**CFN: 2270831
Trak3: 1999-593**