



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 2054 N  
Public Health Service

Central Region

Telephone (973) 526-6009

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

September 3, 1998

**WARNING LETTER**

Lydia Blancato, CEO  
Central Jersey Blood Center  
494 Sycamore Avenue  
Shrewsbury, New Jersey 07702

**File No.: 98-NWJ-36**

Dear Ms. Blancato:

During an inspection of Central Jersey Blood Center (CJBC), located at 494 Sycamore Ave., Shrewsbury, New Jersey on July 1, 2, 6-9, 13, 1998, 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 (CFR), Parts 600-680, as they relate to collecting, processing and testing blood components. These deviations were cited on an FDA 483 List of Inspectional Observations issued to responsible management at CJBC on July 13, 1998.

The significant observations are as follows:

1. Failure to identify and defer an unsuitable donor, in accordance with standard operating procedures. Donor unit #0273667 was collected from a donor who indicated taking Accutane within 30 days of donation; unit was processed, shipped and transfused. [640.3 (a)] and [606.100 (b)]
2. Computer records for Hepatitis B Surface Antigen (HBsAg) EIA test results and interpretation are not accurate. Repeat reactive EIA test results are changed to non-reactive if the supplemental test is not positive. [606.160 (b)(2)(i)]
3. Due to the changing of the HBsAg test results, all unsuitable donors cannot be identified. There is no assurance that your system will identify and permanently defer donors reactive for HBsAg and Hepatitis B Core (HBc), on the same or subsequent donation. [606.160 (e)]
4. Failure to assure that the supplemental test performed by a contract testing laboratory is an FDA licensed neutralization test for HBsAg. Donor re-entry is determined by the results of this test. [606.140(b)]

5. Written procedures were not available for the handling of Hepatitis deferrals, regarding the changing of HBsAg test results and the manual flagging of reactive HBc results for deferral purposes. [606.100(b)]
6. Written procedures were not available for all operations involving the collection of plateletpheresis donors. Current procedures for the use of the Coulter counter for pheresis samples and quality control and maintenance of the pheresis equipment are incomplete. [606.100(b)(2) & 606.100(b)(15)]

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 FDA-483 List of Inspectional Observations, dated August 11, 1998. We understand that several procedures have been developed or revised to address the inspectional concerns, however since your response did not include any supporting documentation, we cannot evaluate the adequacy of your response. We note that you plan to upgrade the current computer system. Your further response should include a timetable of when the computer system validation is expected to be completed.

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, including copies of available documentation demonstrating that corrections have been made and an explanation of actions being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrective measures will be implemented.

Your response should be sent to the New Jersey District Office, FDA, 10 Waterview Blvd., 3<sup>rd</sup> Floor, Parsippany, NJ 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



DOUGLAS ELLSWORTH  
District Director  
New Jersey District, FDA

**CERTIFIED MAIL -**  
**RETURN RECEIPT REQUESTED**