



November 21, 2000

**WARNING LETTER NO. 2001-NOL-03**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Frank A. Riddick, Jr., M.D.  
Chief Executive Officer  
Alton Ochsner Medical Foundation Blood Bank  
1519 Jefferson Highway  
New Orleans, LA 70121

Dear Dr. Riddick:

During an inspection of your blood bank on September 25-29, 2000, our investigators documented serious violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components under Title 21, *Code of Federal Regulations* (21 CFR), Parts 600-680.

The inspection revealed that you failed to adequately determine the suitability of persons who serve as a source of whole blood [21 CFR 640.3(b)]. Donor suitability records indicate that for the period of July 27, 2000 through August 26, 2000, you authorized accepting donors with hematocrits of 35% and within six weeks of their previous donation.

Your blood bank failed to interpret results according to written procedures. For example, your blood bank failed to permanently defer a donor following repeat reactive HBcAb results for two units [21 CFR 606.100]. Although the units were discarded, the first unit's results were officially reported as non-reactive, and the donor was not flagged in your computer as having an initial core reactive unit.

Your blood bank did not have written procedures to accurately relate products to donors [21 CFR 606.100(b)(4) and 21 CFR 606.140(c)]. Since January 1999, your blood bank has had 15 instances of donor/unit mix-ups in which unit number labels were switched on donor records, blood segments were placed in the wrong sample tubes, or pilot tube sets were swapped. Only five of these errors were identified on your problem log sheets. The remaining ten were not consistently investigated to prevent future donor/unit mix-ups.

Also, on September 26, 2000, your laboratory did not follow written procedures and label laboratory tubes for a unit of leukocyte-reduced platelets prior to filling [21 CFR 606.140(c) and 21 CFR 640.4(g)(3)].

Your blood bank continued to use [REDACTED] microhematocrit centrifuge readings to make donor suitability determinations for some whole blood donations and for all apheresis donations, even though an investigation revealed significant, widespread discrepancies between the [REDACTED] reading and the expected range for these readings [21 CFR 640.3].

Your blood bank did not establish or follow written procedures for the plateletpheresis donors with platelet counts less than 150,000 per  $\mu$ l [21 CFR 640.21 (c)]. In April and May 2000, two donors donated platelets on multiple dates, and both donors had pre-pheresis platelet counts less than the platelet counts recommended in the blood bank's SOP. There is no documentation that these donors were evaluated for their pre-donation pheresis counts to determine their suitability.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood and blood components produced and issued by your blood bank are in compliance with the Act and with the CGMP regulations. You should take prompt action to correct these violations. Your failure to correct these violations may result in further regulatory action being taken by FDA 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, including examples of any documentation showing that corrections have been achieved. If you cannot complete corrections within 15 working days, state the reason for the delay and the time period within which corrections will be completed.

Your response should be directed to Patricia K. Schafer, Director, Compliance Branch, U.S. Food and Drug Administration, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127, telephone number (504) 253-4519. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Schafer.

Sincerely,



Carl E. Draper  
District Director  
New Orleans District

Enclosure: Form FDA 483

cc: F. Robert Rodwig, M.D.  
Blood Bank Medical Director  
Alton Ochsner Medical Foundation  
1519 Jefferson Highway  
New Orleans, Louisiana 70121