



July 13, 2001

**WARNING LETTER**

SJN-01-14

Dr. Héctor Martínez  
Medical Director  
Universidad de Ciencias Médicas  
D/b/a/ San Juan Bautista Medical Center  
Call Box 4964  
Caguas, PR 00726

Dear Dr. Martinez:

During an inspection of your unlicensed hospital blood bank from May 8 to May 18, 2001, our investigator documented deviations from the Current Good Manufacturing Practices (GMP's) for Blood and Components, Title 21, Code of Federal Regulations, part 606 (21 CFR 606), General Biological Products Standards (21 CFR 610) and Additional Standards for Human Blood and Blood Products (21 CFR 640). These deviations cause the Blood and Blood products manufactured and tested by your firm to be adulterated within the meaning of section 501 (a) (2) (b) of the Food Drug and Cosmetic Act (the Act).

The specific deviations reported are the following:

1. Failure to ensure that donors with repeatedly reactive serological tests for Hepatitis B Surface antigen (HbsAg) are permanently deferred from subsequent blood donations as required by 21 CFR 610.41. Records for three donors who tested repeatedly reactive for HbsAg were placed in the file for temporary, rather than permanent deferral.
2. Failure to include screening of donors for risk factors for the infectious disease New Variant Creutzfeldt-Jakob (nvCJD) disease as required by 21 CFR 640.3 (b)(6).
3. Failure to assure the reliability and accuracy of test methods and results as required by 21 CFR 606.140 (b). No investigations were performed to determine the cause of unexpected results including sudden increases in reactive rates for Hepatitis B Core antigen screening.
4. Failure to assure that Standard Operating Procedures (SOP's) are maintained with current information as required by 21 CFR 606.100 (b). The following

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recent information was not incorporated into the SOP Manual:

- a) Screening for nvCJD Intended by FDA for immediate implementation not later than April 17, 2001.
- b) Requirements for error and accident reporting to FDA.
- c) Requirements for maintenance of source and disposition records for 10 years.

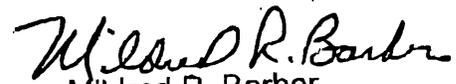
The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes 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 to correct the noted violations and to prevent their 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 address on the letterhead above to the attention of Mary L. Mason, Compliance Officer.

Sincerely,

  
Mildred R. Barber  
District Director

Cc: Lcda. Rosita Esterás  
Hospital Administrator  
Universidad de Ciencias Médicas  
D/b/a San Juan Bautista Medical Center  
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Caguas, PR 00726