



**CERTIFIED MAIL - RETURN RECEIPT REQUESTED**  
**ARTICLE #**

DEC 27 1999 09 27 PM '99

December 17, 1999

THE INTERSTATE COMPANIES

Interstate Blood Bank, Inc.  
Bio-Blood Components, Inc.  
Interstate Blood and Plasma, Inc.  
Plasma Biological Services, Inc.  
Maryland Biological Services, Inc.  
The House of Supply Company

LOCATIONS

INTERSTATE BLOOD BANK, INC.

Chicago, Illinois  
Clarksville, Tennessee  
Killeen, Texas  
Louisville, Kentucky  
Memphis, Tennessee  
Miami, Florida  
Millington, Tennessee  
Milwaukee, Wisconsin  
Nashville, Tennessee  
Philadelphia, Pennsylvania  
St. Louis, Missouri  
Temple, Texas

BIO-BLOOD COMPONENTS, INC.

Columbus, Ohio  
Gary, Indiana  
Hammond, Indiana  
Muskegon, Michigan

INTERSTATE BLOOD AND PLASMA, INC.

Kenosha, Wisconsin  
Madison, Wisconsin  
Wilkes-Barre, Pennsylvania

PLASMA BIOLOGICAL SERVICES, INC.

Asheville, North Carolina  
Columbia, Missouri  
Jackson, Tennessee  
Memphis, Tennessee  
Owensboro, Kentucky

MARYLAND BIOLOGICAL SERVICES, INC.

Baltimore, Maryland

THE HOUSE OF SUPPLY COMPANY

Memphis, Tennessee

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, RM 1061  
Rockville, MD 20852

RE: **Docket No. 98N-0581**

Dear Sirs:

The following are comments on Docket No. 98N-0581, Proposed Rule "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents" appearing in the Federal Register on August 19, 1999.

21 CFR 610.40(b)(2) - We agree with the FDA's exception of blood products for further manufacture into in vitro diagnostic products from testing for HTLV-I and II. However, in "C. Exceptions" of the Description of the Proposed Rule, the statement "Currently, in the FDA's existing guidance, testing for antibodies to HTLV, types I and II is recommended for donors only if blood components, including plasma, are intended for transfusion" is contrary to the information we were given by the Center for Biologics Evaluation and Research (CBER). In January of 1998, CBER ruled that testing for antibodies to HTLV - I and II was required for products collected for the sole purpose of further manufacturing into in vitro diagnostic products. Our company was instructed to comply with the FDA's guidance document. If the statement in the proposed rule is in fact true, we have been performing a test that provided no benefit to the safety of the blood supply and increased our product cost as well the products produced by our customers. This ruling gave an unfair competitive advantage to our competitors who did not implement the test. We respectfully request a response regarding this inconsistency.

Anti-HBC testing - It is unclear whether the intent of the proposed rule is to remain consistent with FDA's September 10, 1991 recommendations on Anti-HBC testing [FDA Recommendations Concerning Testing for antibody to Hepatitis B Core Antigen (Anti-

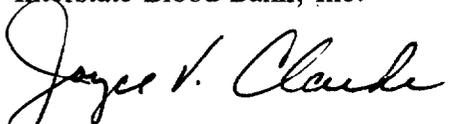
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HBC)] allowing Blood and Blood Components such as Red Blood Cells and Serum intended for use in further manufacture or research be labeled "Not Tested for Anti-HBC". These products have not been tested for anti-HBc in the past. As stated in the present Description of the Proposed Rule "In most cases, blood that is negative for HBsAg but is reactive for anti-HBc would be from a donor who has cleared a hepatitis B infection." We request that the intent of the proposed rule regarding anti-HBc testing of products for further manufacture other than Source Plasma be clarified.

Sincerely,  
Interstate Blood Bank, Inc.



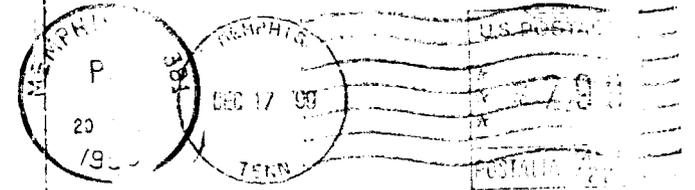
Joyce V. Clarke, MT(ASCP)SBB  
Director, Regulatory Affairs

*Interstate Blood Bank, Inc.*  
3180 Old Getwell Road  
Memphis, Tennessee 38118

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P 241 413 889

MAIL



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Food and Drug Administration  
5630 Fishers Lane, RM 1061  
Rockville, MD 20852**

