Puget Sound
Blood Center
and Program

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July 29, 1999

Dockets Management Branch (HFA–305)
Food and Drug Administration
5630 Fishers Lane, rm. 106
Rockville, MD 20852

and

Office of Information and Regulatory Affairs, OMB
New Executive Office Bldg.
725 17th St. NW., rm. 10235
Washington, DC 20503
Attn: Wendy Taylor
Desk Officer for FDA

Re: Comments to **[Docket No. 99D–1878]**

To Whom It May Concern:

The following comments are submitted to the FDA Guidance for Industry "Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibodies to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV)," **[Docket No. 99D–1878]**:

1. The term "readily retrievable" lacks a standard definition. Further clarification of this term is needed for a firm to assure compliance with the indefinite lookback requirements. The risk of each institution formulating its own policy undermines the uniform public health effort driving lookback.

2. The use of RIBA 1.0 is not addressed in the recommendations for quarantine, disposition and notification of prior collections.

3. Item 3.B.1.(i) is not logical. If the supplemental test is not performed, consignees cannot be notified of the results of supplemental testing.

4. The extension of the recordkeeping requirement established in 21 CFR 606.160 is not consistent with Good Guidance Practices (Federal Register, February 27, 1997), as it does not represent the FDA's current interpretation of regulation. The regulation is very specific in stating an exact time period.

5. The paperwork burden of extending the record retention period from that currently published in 21 CFR 606.160 has not been included in the Paperwork Reduction Act assessment. While less space may be required, the cost associated with the management of records and electronic storage cannot go unaccounted.

These comments have been submitted in duplicate.

Sincerely,

Linda S. Barnes
Manager, Quality Assurance/Regulatory Affairs

99D-1878

C6

Quality Assurance/Regulatory Affairs

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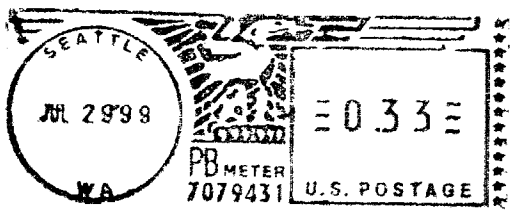

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