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September 2, 2005

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

Re: Docket No. 2005D-0261

To Whom It May Concern:

Listed below are our comments regarding the document *Nucleic Acid Testing for Human Immunodeficiency Virus Type 1 and Hepatitis C Virus: Testing, Product Disposition, and Donor Deferral and Reentry*.

The document is concise and clearly written. The use of flow charts is most helpful and we encourage the FDA to continue to include such aids in future guidance dealing with complex issues such as donor questions, donor re-qualification, testing algorithms, etc.

- The introduction states that this guidance applies to the testing of human blood and blood components. As an establishment that collects both donors for blood and blood components and cellular-based products, we request that the final document state that this guidance should also apply to donors of cellular and tissue-based products.
- The definition for "Additional NAT" states "A NAT that uses an amplification technology and/or primers that are different from those that were used for the original NAT screening test, and that have been validated for use with samples from individual donors. This test is not used to make the initial determination of donor suitability, but is used for donor counseling and to determine whether lookback should include notification of transfusion recipients."
 - Throughout the document Additional NAT is qualified with the statement "we recommend that the test be one that has been validated for use with individual donor samples." Please clarify if the Additional NAT test system must be labeled for donor use or can the test system be labeled for clinical diagnostic use with in-house validation on donor samples.
 - The algorithms indicate that "Additional NAT" results are also used in determining eligibility for re-entry. Consider modifying the last sentence in the definition to include re-entry, for example: *This test is not used to make the initial determination of donor suitability, but is used for donor counseling, donor re-entry, and to determine whether lookback should include notification of transfusion recipients.*

Thank you for your consideration of our comments in formulating the final rule.

Sincerely,



S. Breannan Moore, M.D.
Chair, Division of Transfusion Medicine
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2005D-0261

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cc: Mary Foss, Sheryl Tran