

164 '02 JUL -8 A10 35

July 3, 2002

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

Re: **Docket Number 02D-0096** Guidance for Industry: Use of Nucleic Acid Testis on Pooled and Individual Samples from Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV (March 2002)

Dear Sir or Madam:

New York Blood Center would like to offer comments relative to the Guidance for Industry indicated above. This document relates to the implementation of NAT for HIV-1 and HCV.

1. FDA indicates in Section IV Implementation, that blood establishments will be given six months from publication of the final Guidance to implement a licensed NAT test. To date (7/3/02) only one test has been approved. Approximately 4.5 million samples are still being testing annually under IND. If there is a significant delay in approval of a second test, does FDA have the assurance of the manufacturer of the currently approved test that it can support the transition of the centers using the IND test (infrastructure, equipment, training, test kits) to comply with the 6 month period for implementation? If the timing of licensure of a second test appears to be extended, we suggest that FDA consider an extension to implementation of the final Guidance to ensure that licensed tests from at least two manufacturers are available.
2. The Guidance document does not provide information for the management of blood donors who are found to be NAT+/seronegative for HIV-1 or HCV RNA.
3. The Guidance document does not provide information for the management and disposition of products from donors found to be NAT+/seronegative for HIV-1 or HCV RNA.
4. The Guidance document does not provide information regarding a confirmatory algorithm for donors who are found to be NAT+/seronegative for HIV-1 or HCV RNA.

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5. The Guidance document does not provide information about re-entry algorithms for donors who are NAT+/seronegative for HIV-1 or HCV on the index donation. Will a donor who does not seroconvert in a specified period of time, or whose positive NAT result does not persist over time, be eligible for re-entry
6. Will blood establishments be able to use NAT in confirmatory algorithms or to resolve inconclusive cases? For example, what would be the disposition of a donor who is HIV EIA repeatedly reactive, HIV-1 WB or IFA negative and NAT negative?
7. NYBC is concerned that the proposal for the differential labeling of products tested by pooled NAT or individual NAT may be confusing to the consignees of blood products and may raise complications for inventory management. We encourage FDA to consider alternatives that will allow for a more uniform labeling process.

We thank FDA for its review and response to these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Valinsky". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

Jay E. Valinsky, PhD
Vice President, Information and Technology
For New York Blood Center

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1 From
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