



Puget Sound Blood Center

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May 17, 2005

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

Re: Docket No. 2005D-0133

Draft "Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection"

To Whom It May Concern:

Please accept the following comments.

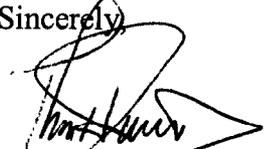
1. Regarding Donor Deferral:

After 120 days from a reactive WNV NAT donor screening test, can a follow-up sample be obtained concurrently with whole blood or apheresis product collection, as long as the collected product is quarantined pending the outcome of IDT NAT?

2. Regarding Biologic Product Deviation and Fatality Reporting:

The Draft Guidance currently states: "We believe that the receipt of post donation information concerning donor illness would be reportable under this section, ..."  
For the purpose of this guidance, the following wording is suggested in order to clarify the rationale for reporting: "We believe that the receipt of post donation information confirming donor WNV infection would be reportable under this section, ..."

Sincerely,



Thomas H. Price, MD  
Medical Director

2005D-0133

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