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

Docket No. 2005D-0133

Comments:

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

Section III. Recommendations for Donor Deferral

A. Diagnosed or Suspected Acute West Nile Virus Illness or Infection

We believe the sentence regarding deferral of a potential donor with medical diagnosis or suspicion of WNV infection to be confusing in light of the fact that the question asking the donor if they have experienced a fever or headache in the past week can now be discontinued. Eliciting this information from the donor may not occur during the donor screening. Is the guidance referring to information about diagnosed or suspected WNV that is voluntarily provided by the donor in response to other questions?

Section IV. Recommendations for Retrieval and Quarantine of Blood and Blood Components Including Recovered Plasma, Source Plasma, and Source Leukocytes

B. Donor Who May Have Transmitted West Nile Virus Infection

This section recommends that the establishment, "conduct prompt product quarantine and retrieval for in-date components collected from the donor of a suspect donation in the period between 120 days before the suspect donation and up to and including 120 days after the suspect donation." This appears to be inconsistent with the recommendation in the previous section (A.), which states. "Relevant collections include those occurring between 14 days prior to onset of illness and up to and including 120 days after diagnosis or onset of illness, which ever is later."

Sincerely,



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