AMERICAN
ASSOCIATION
OF BLOOD BANKS

October 22, 2003

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

Re: Docket 2002D-0467: "Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection" — Final Guidance issued May 2003

Dear Docket Officer:

The American Association of Blood Banks (AABB) appreciates the opportunity to comment on the "Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection."

AABB is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents approximately 2,000 institutional members, including blood collection centers, hospital-based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.

The FDA "Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection Final Guidance" was issued in May 2003, to revise the previously published recommendations for assessing donor suitability and product safety as it relates to West Nile Virus (WNV). The FDA omitted the draft guidance process and instead released this document as a final guidance to be implemented within 30 days. AABB believes that the draft guidance process is important and allows for thoughtful comment that will assist FDA in releasing a final document that is meaningful and practical to implement. **AABB requests that FDA restrict decisions to eliminate the draft guidance process to critical issues that require immediate intervention.** In this instance, there was adequate time to permit discussion prior to issuing a guidance, as previous guidance was in place. **FDA should establish a framework for managing fast-track issues that allows for input from affected stakeholders.**

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The guidance added one question to the donor history questionnaire regarding history of "headache with fever" in the prior week. The requirement to implement a new question within 30 days places undue stress on the cGMP operations at blood collecting facilities. As FDA is aware, the blood collecting facility must describe all processes in standard operating procedures. The facility has cGMP responsibilities for effective staff training and proper record keeping. **Again, the AABB requests that FDA restrict the requirement to implement a new question within 30 days to critical issues where such action is clearly necessary.**

The guidance document provides recommendations that the new question be asked each year between June 1 and November 30; however, it may start earlier and run later in local areas where the medical director is aware of early and/or late WNV activity in the community. The guidance loses uniformity when the medical director is instructed to use discretion in the local area in regard to the start and stop dates. Although we appreciate FDA's attempt to provide flexibility, operationally, adding "turn on/turn off" questions is not very practical.

FDA did not validate the question nor present it to the AABB Uniform Donor History Questionnaire Task Force for validation of donor comprehension regarding "fever." Does it require actual measurement of the temperature, or does it simply refer to the donor feeling that they might have had a temperature? Neither FDA nor CDC offers a definition of fever as it relates to early symptoms of WNV. CDC, for example, associates 100.4 F with the definition of SARS illness. Without validation of donor comprehension, the effectiveness of deferral based on this question is unknown. Validating questions for donor comprehension greatly enhances the safety of the blood supply while lessening negative impacts on the adequacy of the supply caused by meaningless deferrals. The AABB Uniform Donor History Questionnaire Task Force is positioned to work with FDA to ensure questions are validated for donor comprehension prior to inclusion on a questionnaire.

FDA recognizes that WNV is an epidemic threat to the blood supply, with seasonal effects, and has provided instructions for the question regarding fever with headache to be used during the peak season of June through November. Future guidance documents should contain a process for cessation of activities designed to safeguard the blood supply from WNV infection, i.e., an exit strategy for questions and/or any testing that may be in place. This is important in all instances of epidemic threats or emerging threats that may disappear or not materialize. Exit strategies can be communicated in guidance documents by defining triggers whereby required actions cease to be required, or by announcement that the guidance document is withdrawn due to obsolescence. **Once a test has been cleared for use in screening volunteer blood donors, AABB requests that FDA evaluate the value of this question and consider discontinuance of the question at the earliest possible date.**

In conclusion, the AABB is concerned about the safety of patients and donors and requests development of a mutually satisfactory approach to improve FDA recommendations so that the most appropriate and effective interventions can be

established on behalf of patient safety and blood availability. We agree with Commissioner McClellan that "the agency must have productive relationships with its partners to plan, implement and evaluate our risk management strategies." (FDA's Strategic Action Plan for Protecting and Advancing America's Health: Responding to New Challenges and Opportunities, August 2003). The blood banking community stands ready to interact with FDA as needed.

Questions concerning these comments may be directed to Allene Carr-Greer, Deputy Director, Regulatory Affairs, AABB (acarrgreer@aabb.org).

Sincerely,

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Chief Executive Officer