

NATIONAL HEMOPHILIA FOUNDATION

for all bleeding disorders

1092 5 MAY 16 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
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Re: Docket No. 2005-0133

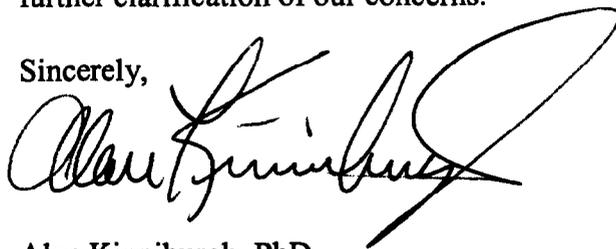
To whom it may concern,

Thank you for the opportunity to comment on the *Draft Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Infection* published in the Federal Register on April 20, 2005.

The National Hemophilia Foundation (NHF) is a national voluntary health organization seeking to cure coagulation disorders through education, advocacy and research. The Blood Safety Working Group of the NHF has reviewed the draft guidance and supports the majority of the document as written. However, we are writing to request that you strongly consider avoiding the use of specific start (May 1) and end (November 30) dates to both define the WNV season and to guide the use of donor deferral questions for WNV. Our concern arises from the fact that, not only will the onset of the "WNV season" vary regionally, but donors may travel/live across regions and, thus have exposure histories that do not reflect that anticipated by the local donor center. Consequently, the selective regional implementation of capture questions may be less effective than desired. The group believes that the implementation of consistently administered questions that better define the constellation of symptoms more specific to WNV would better protect our blood supply.

We thank you for the opportunity to comment. Please contact Neil Frick, Associate Director of Communications and Information Services at 212-328-3708 if you wish further clarification of our concerns.

Sincerely,



Alan Kinniburgh, PhD
Chief Executive Officer

2005D-0133