

Guidance for Industry

Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection

This guidance is being distributed for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without seeking prior comment because the agency has determined that prior public participation is not feasible or appropriate because blood establishments need to establish suitable Standard Operating Procedures as soon as possible in preparation for the season during which an outbreak of West Nile Virus (WNV) can occur.

FDA invites comments on this guidance. Submit comments at anytime to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*. FDA will review any comments we receive and revise the guidance when appropriate.

Additional copies of this guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448 or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at <http://www.fda.gov/cber/guidelines.htm>.

For questions on the content of this guidance, contact the Division of Blood Applications at 301-827-3524.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance document removes our previously published recommendation concerning fever with headache possibly related to West Nile Virus (WNV) infection. Previously, we recommended asking donors each year between June 1 and November 30 whether the donor had a history of fever with headache in the past week, and recommended deferral if the donor provided a positive response. We no longer recommend asking this question or making a deferral on this basis as it relates to WNV.

This guidance applies to Whole Blood and blood components intended for transfusion, and blood components intended for use in further manufacturing into injectable products or non-injectable products, including recovered plasma, Source Leukocytes and Source Plasma. Within this document, “donors” refers to donors of all such products and “you” refers to blood establishments.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

Contains Nonbinding Recommendations

II. DISCONTINUATION OF DONOR DEFERRAL RELATED TO RECENT FEVER WITH HEADACHE AS A SYMPTOM OF WEST NILE VIRUS INFECTION

On October 25, 2002, we issued guidance to industry “Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection”. On May 1, 2003, we issued revised guidance to industry to include deferral of donors who reported fever with headache in the week before donation.

At the time we issued the May 2003 revised guidance, limited donor interview data were available regarding possible WNV-related symptoms that occurred in a period of three weeks prior to donations that were implicated in WNV transmission. Based upon the potential for a combination of these symptoms to be predictive of early WNV infection with minimal non-specific loss of donors, we recommended that you defer from donation for 28 days donors reporting fever with headache in the week prior to donation. We recognized at that time that symptoms occur in only approximately 20 percent of persons infected with WNV and that only a limited proportion of donors known to have been implicated in WNV transfusion-transmission reported symptoms prior to donation.

Data presented at the October 22, 2004, Blood Products Advisory Committee Meeting (Ref. 1) indicated that self-reported fever with headache in the past week before donation did not appear to be predictive of WNV infection and did not correlate with peak periods of WNV incidence as determined by WNV nucleic acid testing (NAT) prevalence in the donor pool. Based upon these data, we are removing from the May 2003 guidance the recommendation for donor deferral based upon a reported history of fever with headache in the week prior to donation.

This guidance pertains solely to our prior recommendation regarding a specific question related to WNV infection. All other donor and blood product management recommendations from the May 2003 guidance remain unchanged.

We consider the deletion of this question from your Standard Operating Procedures (SOPs) to be a change that has minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product. Thus, consistent with FDA’s regulations regarding changes to an approved application, you may report a change to your SOPs to delete the WNV question in an annual report (21 Code of Federal Regulations 601.12(d)).

III. REFERENCES

1. Blood Products Advisory Committee meeting, October 22, 2004 (<http://www.fda.gov/ohrms/dockets/ac/04/transcripts/2004-4074t2.htm>).