

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0045]

Behavior-Based Blood Donor Deferrals in the Era of Nucleic Acid Testing; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled “Behavior-Based Blood Donor Deferrals in the Era of Nucleic Acid Testing (NAT).” The purpose of the public workshop is to address regulatory and scientific challenges and opportunities in the development of policy concerning protection of the blood supply from transfusion-transmissible diseases by deferring blood donors based on high-risk behavior, and to request comments on this topic.

Date and Time: The public workshop will be held on March 8, 2006, from 8 a.m. to 5:30 p.m. The deadline for registration via mail, fax, or e-mail is February 17, 2006 (see *Registration*). Written or electronic comments will be accepted until [*insert date 90 days after date of publication in the* **Federal Register**] (see *Comments*).

Addresses: The public workshop will be held at the National Institutes of Health, Lister Hill Auditorium, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: Rhonda.Dawson@fda.hhs.gov.

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, and telephone and fax numbers) to Rhonda Dawson (see *Contact Person*) by February 17, 2006. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 7:15 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

Comments: Regardless of attendance at the public workshop, interested persons may submit to the Division of Dockets Management (see *Addresses*) written or electronic comments regarding the public workshop. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the public workshop is to address regulatory and scientific challenges and opportunities in the development of policy concerning protection of the blood supply from transfusion-

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transmissible diseases by deferring blood donors based on high-risk behavior. The public workshop will feature presentations by national and international experts from government and academic institutions and industry. The following discussions will be included:

- Current practices in the United States and in foreign countries regarding blood donor deferrals based on high-risk behavior,
- Comparison of selected tissue donor deferral policies to blood donor deferral policies,
 - Behavioral risks for transfusion-transmitted diseases,
 - Residual risks of infection from transfusion, and
 - Potential alternative approaches to donor screening and testing.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: January 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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