health. FDA said that the proposed changes would be an important step toward global harmonization of safety reporting requirements and additional efforts are underway within the Department of Health and Human Services to harmonize the reporting requirements of U.S. Federal agencies (e.g., FDA and the National Institutes of Health are continuing to work together to address the best ways to streamline information sharing and to harmonize, to the extent possible, the safety reporting requirements of the two agencies).

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1587 Filed 2–6–06; 8:45 am]

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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 May 8, 2006 (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-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.

[FR Doc. E6–1588 Filed 2–6–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Independent Evaluation of the Food and Drug Administration's First Cycle Review Performance—Retrospective Analysis Final Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled ''Independent Evaluation of FDA's First Cycle Review Performance—Retrospective Analysis Final Report.'' This report describes an independent evaluation of the issues associated with FDA's conduct of first cycle reviews of new molecular entities for new drug applications (NMEs for NDAs), and biological license applications (BLAs). Applications covered by the report are those submitted to FDA in fiscal years 2002 to 2004. This independent study was conducted in relation to the Prescription Drug User Fee Amendments of 2002 (PDUFA III). This assessment includes a detailed evaluation of the events that occurred during the review process with a focus on identifying the best practices by FDA and industry that facilitated that process.

ADDRESSES: Submit written requests for single copies of this report to the Office of Planning (HFP–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit electronic requests to *Carolyn.Staples@fda.hhs.gov*. This