

- (2) Contemporary Issues in Risk Assessment;
- (3) Postmarket Surveillance—Beyond Passive Surveillance;
- (4) The Food Safety Initiative—The Risk Perspective;
- (5) New Scientific Perspectives: Women's Health and the Science of Gender Differences; and
- (6) Risk Assessment in Action.

If you need special accommodations due to a disability, please contact the American Association of Pharmaceutical Scientists at least 3 weeks in advance.

Dated: November 17, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Donor Suitability Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Blood Donor Suitability Workshop." The purpose of the public workshop is to provide an open forum for discussion of specific donor suitability issues associated with donor deferrals.

Date and Time: The public workshop will be held on December 9, 1999, 8 a.m. to 5 p.m.

Location: The public workshop will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX 301-827-2843.

For information regarding the public workshop and registration: Therese Burke, Laurel Consulting Group, 1815 Fort Meyer Dr., suite 300, Arlington, VA 22209, 703-351-7676, FAX 703-528-0716, E-mail: tburke@lcgnet.com.

Registration: Early registration is recommended on or before November 26, 1999. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Therese Burke (address above). Registration at the site will be

done on a space available basis on the day of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Therese Burke at least 7 days in advance.

Agenda: FDA is holding a public workshop to gather scientific data on specific donor suitability issues affecting donor deferrals and to evaluate how these donor deferrals may affect the nation's blood supply. The three key topics to be discussed at the workshop include: (1) Donor deferral registries, including deferral registries that are used in-house, at mobile collection sites, as well as registries shared by several facilities; (2) minimum donor weight and adjustment of blood volume based on body weight; and (3) deferral of donors who have a history of cancer.

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. The public workshop transcript will also be available on the Center for Biologics Evaluation and Research website at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: November 17, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Workshop on Implementation of Nucleic Acid Testing; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Implementation of Nucleic Acid Testing." The purpose of the public workshop is to discuss the progress in implementation of nucleic acid testing for screening blood and plasma donors.

Date and Time: The public workshop will be held on December 14, 1999, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the National Institutes of

Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD 20892.

Contacts:

For information regarding this notice: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX 301-827-2843.

For information regarding registration: Jennifer Gormley, Laurel Consulting Group, 1815 Fort Meyer Dr., suite 300, Arlington, VA 22209, 703-351-7676, FAX: 703-528-0716, e-mail: jgormley@lcgnet.com.

Registration: Early registration is recommended on or before Friday, November 26, 1999. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Jennifer Gormley (address above). Registration at the site will be on a space available basis on the day of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Jennifer Gormley at least 7 days in advance.

Agenda: FDA is holding a public workshop to evaluate progress in the implementation of nucleic acid testing (NAT) for screening blood and plasma donors. The goals of the public workshop are to: (1) Examine technological advances and current experience with testing plasma pools for hepatitis C virus (HCV), hepatitis B virus (HBV) and human immunodeficiency virus (HIV); (2) discuss issues in the implementation of NAT; (3) evaluate the application of NAT to other transmitted viruses; and (4) monitor progress towards single donation testing. The scientific information obtained from these discussions will provide FDA with a better understanding of the utility of nucleic acid testing of plasma pools in reducing the residual risk of infectious disease transmission from window period donations. In addition, FDA will be able to evaluate progress towards single unit testing by NAT for future implementation in screening blood and plasma donors.

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 meeting at a cost of 10 cents per page. In addition, the transcript will be placed on the FDA web site at www.fda.gov/cber/minutes/workshop-min.htm.