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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@lcnnet.com.

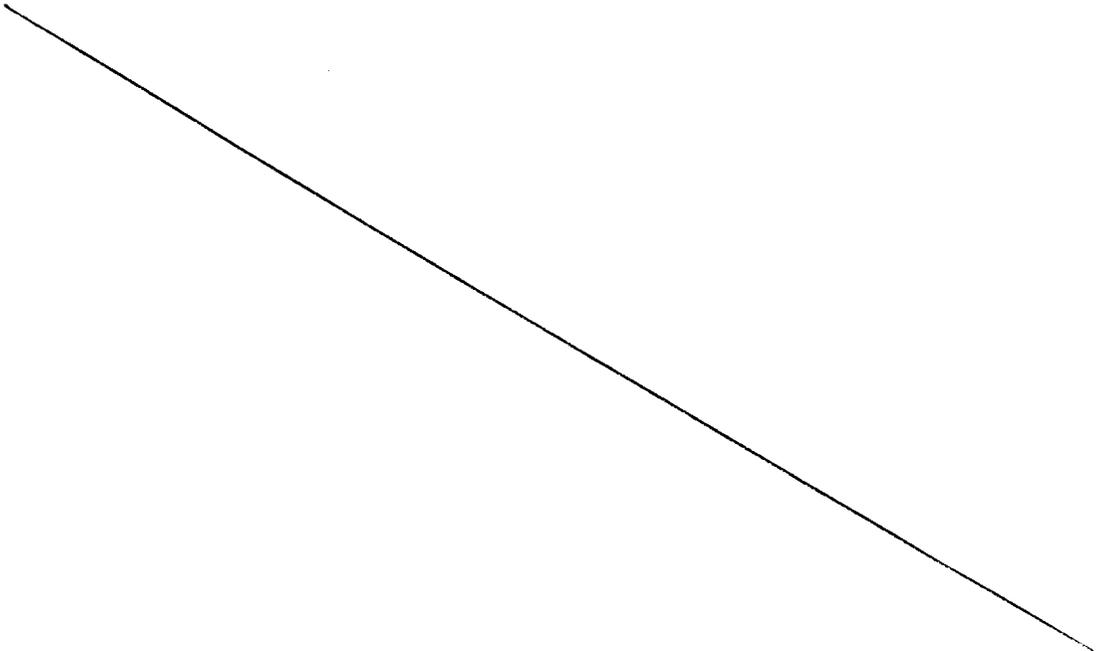
Registration: Early registration is recommended on or before Friday, November 26, 1999. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Jennifer Gormley (address above). Registration at the site will be on a space available basis on the day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

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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.

Dated: 11/17/99
November 17, 1999



William K. Hubbard
Senior Associate Commissioner for Policy,
Planning, and Legislation

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