

your comments and recommendations on the draft guidance document. The draft guidance will be announced in the **Federal Register** for public comment and posted on the Internet at <http://www.fda.gov/cber/guidelines.htm>.

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

Dated: October 30, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-27643 Filed 11-02-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Application of Nucleic Acid Testing to Blood Borne Pathogens and Emerging Technologies; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Application of Nucleic Acid Testing to Blood Borne Pathogens and Emerging Technologies." The purpose of the public workshop is to focus on issues surrounding the implementation of nucleic acid testing (NAT) to screen blood and plasma donors.

**Date and Time:** The 2-day public workshop will be held on December 4 and 5, 2001, from 8:30 a.m. to 5 p.m.

**Location:** The public workshop will be held at the Lister Hill Center, National Institutes of Health, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD.

**Contact:** Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX 301-827-2843, e-mail: [wilczek@cber.fda.gov](mailto:wilczek@cber.fda.gov).

**Registration:** Preregistration is not required. However, early registration is recommended because there are only 175 seats at the site. Registration at the site will be done on a space available basis on the days of the workshop, beginning at 7:30 a.m. Mail, e-mail, or

fax your registration information (including name, title, firm name, address, telephone and fax number, and e-mail address) to the contact person on or before November 23, 2001. A registration form is available on the Internet at <http://www.fda.gov/cber/scireg.htm>. There is no registration fee. If you need special accommodations due to a disability, please contact Joseph Wilczek (address above) at least 7 days in advance.

**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. The public workshop transcript will also be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

**SUPPLEMENTARY INFORMATION:** FDA is sponsoring a public workshop on issues surrounding the implementation of NAT for blood borne pathogens. These issues for testing blood and plasma donors include screening for human immunodeficiency virus, hepatitis C virus, hepatitis B virus, and testing manufacturing pools for hepatitis A virus and parvovirus B-19. The goals of the public workshop are to examine: (1) International developments and regulatory issues regarding the implementation of minipool and single unit NAT; (2) standardization and quality assurance of NAT methods; (3) industry experience with minipool NAT for donor screening and in-process plasma pools; (4) potential replacement of current viral marker tests by NAT; and (5) emerging issues in nucleic acid testing, including new pathogens and new screening technologies. Another goal of the workshop is to evaluate future directions in NAT for blood borne pathogens. The public workshop agenda is posted on the Internet at <http://www.fda.gov/cber/scireg.htm>.

Dated: October 29, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Maternal and Child Health Federal Set-Aside Program; Project Grants; Hana Health Initiative for Children and Adolescents

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of grant award.

**SUMMARY:** The Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA), is awarding a grant for \$1,000,000 in fiscal year (FY) 2001 to the Hana Community Health Center in Hana, Hawaii. The grant supports expansion of health services to children and adolescents, with a focus on addressing special needs of Native Hawaiians in the community of Hana. The award was made from funds appropriated under Public Law 106-554 (HHS Appropriation Act for FY 2001). This project is a Special Project of Regional and National Significance (SPRANS) authorized by section 501(a)(2) of the Social Security Act, the Maternal and Child Health Federal Set-Aside Program.

**Purpose:** HRSA determined that it was necessary to provide funds to the community of Hana for expanded emergency, health and related services to children and adolescents in Hana, with services to have a Native Hawaiian focus. The primary source of health care for Hana is the Hana Community Health Center. To seek another source of health care residents must travel two and one-half to three hours, one way, to the main town of Wailuku.

In FY 2001, community surveys indicated a continuing need for funds for the on-site health services supported through this project, which was initiated in 1999 through MCHB's Emergency Medical Services for Children program. Concerns were raised about the need for quality primary and related health care services and the maintenance of 24 hour coverage, especially emergency care. As this is an isolated community with limited health and human services there was a desire to expand the services of the Hana Community Health Center. Maternal and Child Health SPRANS funds were designated to continue to address these services. This project reflects input and participation from the State of Hawaii and the Hana-based community health center and service providers. It provides a comprehensive strategy for: (1)