marketed animal drugs and potential manufacturing problems. Data already on file with FDA is not adequate because animal drug effects can change over time and less apparent effects may take years to manifest themselves. Reports are reviewed along with those previously submitted for a particular drug to determine if any change is needed in the product or labeling, such as package insert changes, dosage changes, additional warnings or contraindications, or product reformulation.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA Forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Likewise, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own detection of a problem or complaints from product users or their veterinarians using FDA Forms 1932 and 1932a . FDA Form 2301 is available for the required transmittal of periodic reports and promotional material for new animal drugs. Respondents to this collection of information are applicants of approved NADAs.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 2301 ...	510.302(a)	190	13.16	2,500	0.5	1,250
Form FDA 1932 ...	510.302(b)	190	94.74	18,000	1.0	18,000
Form FDA 1932a (voluntary)	510.302(b)	100	1.0	100	1.0	100
Total burden hours						19,350

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Response per Recordkeeper	Hours per Recordkeeper	Total Hours
510.300(a) and 510.301(a)	190	13.16	2,500	10.35	25,875
510.300(b) and 510.301(b)	190	94.74	18,000	0.50	9,000
Total burden hours					34,875

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e., adverse drug reaction, lack of effectiveness, and product defect reports) are derived from agency records and experience.

Dated: October 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–27641 Filed 11–2–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0489]

Draft FDA Guidance on the Establishment and Operation of Clinical Trial Data Monitoring Committees; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH), is announcing the following public meeting: Draft FDA Guidance on the Establishment and Operation of Clinical Trial Data Monitoring Committees (DMCs). The topics to be discussed are addressed in the draft entitled ''Guidance for Clinical Trial Sponsors On the Establishment and Operation of Data Monitoring Committee.'' These topics include: The history of DMCs, the types of clinical trials in which DMCs are most important, DMC membership and operations, independence of DMCs, and the regulatory requirements relevant to DMCs.

Date and Time: The meeting will be held on November 27, 2001, from 9 a.m. to 5 p.m.

Location: The meeting will be held at The Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact: Melanie Whelan, Center for Biologics Evaluation and Research (HFM–40), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3841, FAX 301–827–3843, or e-mail: Whelan@cber.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), to Melanie Whelan (address above) by November 20, 2001. We encourage early registration because seating is limited. There is no registration fee.

If you need special accommodations due to a disability, please contact Melanie Whelan at least 7 days in advance.

SUPPLEMENTARY INFORMATION: This meeting will provide a forum for all members of the public to express their opinions and suggestions on the draft entitled ''Guidance for Clinical Trial Sponsors On the Establishment and Operation of Data Monitoring Committees.'' The draft guidance is intended to address scientific, ethical, and practical issues related to the establishment and operation of DMCs for clinical trials. The meeting will be of primary interest to sponsors of clinical trials evaluating FDA-regulated products. The objectives of the meeting are to: (1) Present the material in the draft guidance document and (2) solicit

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*.

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.

[FR Doc. 01–27644 Filed 11–2–01; 8:45 am]

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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)