

and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurances must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of the IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities: It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaska Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947-47951 (a copy is included in the application kit).

Pre- and Post-test Counseling and Partner Notification: Recipients are required to provide HIV antibody testing to determine a person's HIV infection status; therefore, they must comply with State laws and regulations and CDC guidelines regarding pre- and post-test counseling and partner notification of HIV-seropositive patients. A copy of the guidelines will be included in the application kit. Recipients must also comply with State and local health department requirements relating to specific reportable diseases or conditions. Recipients must provide referrals for HIV diagnosis and treatment.

HIV/AIDS Requirements: Recipients must comply with the document entitled "Content of AIDS-Related Written Materials, Pictorials,

Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions" (June 1992), a copy of which is included in the application kit. In complying with the requirements for a program review panel, recipients are encouraged to use an existing program review panel such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a government health department consistent with the Content guidelines. The names of the review panel members must be listed on the Assurance of Compliance form (CDC 0.1113), which is included in the application kit.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (OMB Number 0937-0189) must be submitted to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road NE., Room 300, Mailstop E-15, Atlanta, GA 30305, on or before July 1, 1996.

1. **Deadline:** Applications shall be considered as meeting the deadline if they are either:

- (a) Received on or before the deadline date, or
- (b) Sent on or before the deadline date and received in time for submission to the objective review committee. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. **Late Applications:** Applications that do not meet the criteria in 1. (a) or 1. (b) are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

Questions on application procedures and the application package, and business management technical assistance may be obtained from Manuel Lambrinos, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-15, Atlanta, GA 30305, telephone (404) 842-6777, or Internet address: MYL5@opsppg1.em.cdc.gov.

Programmatic technical assistance may be obtained from Veronica Greene, D.D.S., M.P.H., Division of Tuberculosis Elimination, National Center for STD, HIV, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-10, Atlanta, GA 30333, telephone (404) 639-8123.

Please refer to Announcement Number 619 when requesting information or submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report, Stock No. 017-001-00473-1) referenced in the *Introduction* through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: April 24, 1996.

Joseph R. Carter,
Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).
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BILLING CODE 4163-18-P

The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention Announces the Following Meeting

Name: Scientific and Technical Discussion of the Draft Document, "Criteria for a Recommended Standard: Occupational Exposures to Metalworking Fluids (MWFs)." **Times and Dates:** 9 a.m.-5:30 p.m., June 13, 1996, 9 a.m.-5:30 p.m., June 14, 1996. **Place:** Drawbridge Inn, Yeomans Hall, I-75 and Buttermilk Pike, Fort Mitchell, Kentucky 41017.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The purpose of this meeting is to discuss the scientific and technical content of the draft NIOSH document, "Criteria For a Recommended Standard: Occupational Exposures to Metalworking Fluids (MWFs)," prior to finalizing the criteria document for publication and transmittal to the Department of Labor. This review will focus on all aspects of the criteria document including: composition and formulation of MWFs, potential adverse health effects from exposure to MWFs, occupational exposure data, and the feasibility of controlling exposures to the NIOSH recommended exposure limit of 0.5 mg/m³ (total particulate).

Contact Persons for More Information: Technical information may be obtained from Brenda Boutin, NIOSH, CDC, 4676 Columbia Parkway, M/S C-32, Cincinnati, Ohio 45226, telephone 513/533-8345, e-mail address: hhal@NIOSDT1.em.cdc.gov.

Persons wishing to attend or make a presentation at the meeting, obtain a copy of

the criteria document, or reserve overnight accommodations at the Drawbridge Inn, should respond by May 10, 1996, to Kellie Wilson, NIOSH, 4676 Columbia Parkway, M/ S C-34, Cincinnati, Ohio 45226, telephone 513/533-8362, fax 513/533-8588, e-mail address: kmp0@NIOSDT1.em.cdc.gov. Information may also be obtained by calling 1-800-35-*NIOSH* or by the Internet NIOSH Homepage: <http://www.cdc.gov/niosh/homepage.html>.

Dated: April 23, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

{FR Doc. 96-10601 Filed 4-29-96; 8:45 am}

BILLING CODE 4160-19-M

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Dental Drug Products Panel Plaque Subcommittee (Nonprescription Drugs) of the Medical Devices Advisory Committee

Date, time, and place. June 6 and 7, 1996, 8 a.m., Holiday Inn—Gaithersburg, Goshen Room, Two

Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person.

Open public hearing, June 6, 1996, 8 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 5 p.m.; open public hearing, June 7, 1996, 8 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 5 p.m.; Jeanne L. Ripperer or Stephanie Mason, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 1600 Rockville Pike, Rockville, MD 20857, 301-827-2244, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Dental Products Panel of the Medical Devices Advisory Committee, code 12518. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

The Dental Products Panel of the Medical Devices Advisory Committee functions at times as a nonprescription drug advisory panel. As such, the panel reviews and evaluates available data concerning the safety and effectiveness of active ingredients, and combinations thereof, of various currently marketed nonprescription drug products for human use, the adequacy of their labeling, and advises the Commissioner of Food and Drugs on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Those desiring to make formal presentations should notify the contact person before May 24, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open subcommittee discussion. On June 6, 1996, the subcommittee will continue its discussion concerning the alcohol content of oral health care mouthwash drug products begun at its June 28 and 29, 1994, meeting. On June 7, 1996, the subcommittee will continue its discussion of hydrogen peroxide, sodium bicarbonate, the combination of hydrogen peroxide and sodium

bicarbonate, and sanguinaria. The subcommittee will also begin a discussion of sodium lauryl sulfate. For further information on the agenda of this meeting, see the background document published elsewhere in this issue of the Federal Register.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.