

National Vaccine Advisory Committee (NVAC), Subcommittee on Vaccine Safety and the Advisory Commission on Childhood Vaccines (ACCV) Subcommittee on Vaccine Safety, Subcommittee on Immunization Coverage, and Subcommittee on Future Vaccines: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following Federal advisory committee meetings.

Name: National Vaccine Advisory Committee (NVAC).

Times and Dates: 8:30 a.m.–2:30 p.m., January 22, 1995. 8:30 a.m.–1 p.m., January 23, 1996.

Place: Savoy Suites Georgetown, 2505 Wisconsin Avenue, NW, Washington, DC 20007.

Status: Open to the public, limited only by the space available.

Purpose: The Committee shall advise and make recommendations to the Director of the National Vaccine Program on matters related to the Program responsibilities.

Matters to be Discussed: The Committee will receive an update on the National Vaccine Program Office and National Vaccine Advisory Committee operations; update on the Interagency Task Force on Vaccine Safety and funding for acting surveillance; update on immunization deliver: insights from recent research on vaccine coverage and a report on the new Women, Infants, and Children demonstration projects; update on vaccine program funding; update from the subcommittee on immunization coverage; proposal for a potential solution to the problem of an increasing menu of pediatric vaccines; defining a vaccine manufacturer/government partnership; update on adult immunization strategies and priorities; report on the influenza pandemic plan; role of the NVAC in fostering the pandemic influenza plan; update on the future vaccines subcommittee; presentation on the presence of reverse transcriptase activity in vaccine products; status of the Advisory Committee on Immunization Practices reevaluation of polio immunization recommendations and adolescent immunization; update on the injury compensation system; an update on USAID; and an information presentation on recent immunization compensation cases impacting immunization.

Name: Subcommittee on Vaccine Safety and the Advisory Commission on Childhood Vaccines Subcommittee on Vaccine Safety.

Time and Date: 2:30 p.m.–5 p.m., January 22, 1996

Place: Savoy Suites Georgetown, 2505 Wisconsin Avenue, NW, Washington, DC 20007.

Status: Open to the public, limited only by the space available.

Purpose: This joint ACCV/NVAC subcommittee will review issues relevant to vaccine safety and adverse reactions to vaccines.

Matters to be Discussed: The Subcommittee will discuss the Institute of

Medicine vaccine safety forum and summary of planned workshops; the task force on safer childhood vaccines; and the charge of the Subcommittees.

Name: Subcommittee on Immunization Coverage.

Time and Date: 2:30 p.m.–5 p.m., January 22, 1996

Place: Savoy Suites Georgetown, 2505 Wisconsin Avenue, NW, Washington, DC 20007.

Status: Open to the public, limited only by the space available.

Purpose: The Subcommittee on Immunization Coverage will identify strategies and policy options by which to further improve the levels of immunization coverage.

Matters to be Discussed: The Subcommittee will discuss determinants of under vaccination in preschool children; national, State, and local immunization coverage levels; current interventions for immunization and the future health environment.

Name: Subcommittee on Future Vaccines.

Time and Date: 2:30 p.m.–5 p.m., January 22, 1996.

Place: Savoy Suites Georgetown, 2505 Wisconsin Avenue, NW, Washington, DC 20007.

Status: Open to the public, limited only by the space available.

Purpose: The Subcommittee on Future Vaccines will develop policy options and guide national activities which will lead to accelerated development, licensure, and best use of new vaccines in the simplest possible immunization schedules.

Matters to be Discussed: The Subcommittee will review and discuss the terms of reference for the Subcommittee; identify the matrix of interactions and partnerships, via specific case studies; describe the process of priority-setting by each of the members of the vaccine research and development community, and define barriers to new vaccine development.

Agenda items for each meeting are subject to change as priorities dictate.

The shutdown of the Federal Government prevented meeting the 15-day publication requirement.

Contact Person for More Information:

Gloria A. Kovach, Committee Management Specialist, National Vaccine Program Office, CDC, 1600 Clifton Road, NE, M/S A20, Atlanta, Georgia 30333, telephon 404/639-3851.

Dated: January 10, 1996.

Carolyn J. Russell,

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

[FR Doc. 96-487 Filed 1-11-96; 8:45 am]

BILLING CODE 4163-18-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:

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time and place. January 29, 1996, 8:30 a.m., rm. 020B, 9200 Corporate Blvd, Rockville, MD. Attendees with a disability requiring special accommodations should contact Ed Rugenstein, Sociometrics, Inc., 301-608-2151.

Type of meeting and contact person. Open public hearing, January 29, 1996, 8:30 a.m. to 9:30 a.m., unless public participation interest does not last that long; open committee discussion, 9:30 a.m. to 1:30 p.m.; Ramiah Subramanian Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8320, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, D.C. area), Circulatory System Devices Panel, code 12625.

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.

Agenda—Open public hearing. Interested persons may present data,

information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 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 committee discussion. On January 29, 1996, the committee will discuss clinical data requirements (experimental designs, protocols, quality assurance, etc.) to be incorporated in a draft guidance for Automatic Implantable Pacer Cardioverter Defibrillator (AIPCD) submissions. Single copies of the draft guidance document will be available from the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 800-638-2041 or 301-443-6597.

FDA regrets that it was unable to publish this notice 15 days prior to the January 29, 1996, Circulatory System Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency feels that the issue needs to be brought to public discussion urgently and qualified members of the Advisory Panel were available at this time, the agency decided that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion 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 transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: January 5, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
[FR Doc. 96-470 Filed 1-11-96; 4:33 pm]
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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Extension of Comment Period on the Draft Environmental Impact Statement and Application for the Proposed Issuance of a Permit To Allow Incidental Take of Threatened and Endangered Species on Plum Creek Timber Company, L.P., Lands in the I-90 Corridor, King and Kittitas Counties, Washington

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice, extension of comment period.

SUMMARY: This notice advises the public that the U. S. Fish and Wildlife Service is extending the comment period for the Draft Environmental Impact Statement (DEIS) and the application for the proposed issuance of an incidental take permit (PRT-808398) to Plum Creek Timber Company, L.P. . This notice is provided pursuant to section 10(c) of the Endangered Species Act and National Environmental Policy Act regulations.

DATES: Written comments on the permit application and DEIS should be received on or before January 22, 1996.

ADDRESSES: Comments regarding the application or DEIS, or requests for those documents, should be addressed to William Vogel, U. S. Fish and Wildlife Service, Pacific Northwest Habitat Conservation Plan Program, 3773 Martin Way East, Building C—Suite 101, Olympia, Washington 98501; (360) 534-9330. Please refer to permit No. PRT-808398 when submitting comments. Individuals wishing copies of the documents for review should immediately contact the office listed above.

FOR FURTHER INFORMATION CONTACT: William Vogel, U. S. Fish and Wildlife Service, or Steve Landino, National Marine Fisheries Service, at the office listed above.

SUPPLEMENTARY INFORMATION: On November 17, 1995 (60 FR 222:57722-57724), the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together the Services) announced the availability of a Draft Environmental Impact Statement and the receipt of an application for the