implant to Canada. The product is intended for implanting in the ear of cattle for increased rate of weight gain and improved feed conversion of weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers, and increased rate of weight gain in suckling beef calves. The application was received and filed in the Center for Veterinary Medicine on December 7, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by February 20, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.44).

Dated: January 26, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–2596 Filed 2–6–96; 8:45 am]

BILLING CODE 4160–01–F

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 Products Panel of the Medical Devices Advisory Committee

Date, time, and place. February 27, 28, and 29, 1996, 8 a.m., Bethesda Marriott Hotel, Grand Ballroom, 5151 Pooks Hill Rd., Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–897–9400 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, February 27, 1996, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; closed committee deliberations, 5 p.m. to 6 p.m.; open public hearing, February 28, 1996, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 6 p.m.; open public hearing, February 29, 1996, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 6 p.m.; Carolyn A. Tylenda, Center for Devices and Radiological Health (HFZ–420), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Dental Products Panel, code 12518.

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 February 20, 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 February 27, 1996, the committee will discuss and vote on a premarket approval application (PMA) for a bone filling device for periodontal use. On February 28, 1996, the committee will: (1) Discuss and vote on a PMA for a dental laser for hard tissue use, and (2) discuss the reliability and accuracy of digital subtraction radiography and its use in the clinical design of trials evaluating treatment and/or progression of periodontitis. On February 29, 1996, the committee, with representation from the Dental Drug Products Plaque Subcommittee, will discuss public health issues relevant to a new drug application (NDA) 20–231, a triclosan/fluoride dentifrice, sponsored by Colgate-Palmolive, for use in the prevention of caries, plaque, and gingivitis.

Closed committee deliberations. On February 27, 1996, FDA staff will present to the committee trade secret and/or confidential commercial information regarding dental device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate 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.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

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 31, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–2597 Filed 2–6–96; 8:45 am]

BILLING CODE 4160–01–F

Substance Abuse and Mental Health Services Administration

Notice of Rescheduled Meeting Dates

Pursuant to Public Law 92–463, notice is hereby given of the rescheduled meetings of the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council and Advisory Committee for Women's Services in February 1996.

The meeting of SAMHSA National Advisory Council will include discussions concerning SAMHSA's Reauthorization; SAMHSA's Managed Care Initiative, including the role of SAMHSA in developing mental health and substance abuse standards for managed care facilities; a report on the National Co-Morbidity Survey; a report on the National Conference on Co-Occurring Disorders; and a presentation on the Methodologies and Estimates of Incidence and Prevalence of Seriously Mentally Ill (SMI) Adults. In addition, the staff of an exemplary community-based program will describe their efforts to treat addictive disorders. Attendance by the public will be limited to space available.

The committee will also review, discuss and evaluate contract proposals. Therefore, a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(3), (4) and (6) and 5 U.S.C. app. 2 10(d).

A summary of the meeting and a roster of Council members may be obtained from: Ms. Susan E. Day, Program Assistant, SAMHSA National Advisory Council, 5600 Fishers Lane, Room 12C–15, Rockville, Maryland 20857. Telephone: (301) 443–4640.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Substance Abuse and Mental Health Services Administration National Advisory Council.

Meeting Date: February 26, 1996.

Place: Omni-Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC 20008.

Open: February 26, 1996, 9:00 a.m. to 5:30 p.m.

Closed: February 26, 1996, 5:45 p.m. to 7:00 p.m.

Contact: Toian Vaughn, Room 12C–15, Parklawn Building, Telephone: (301) 443–4640 and FAX: (301) 443–1450.

The meeting of the Advisory Committee for Women's Services will include a discussion of and update on policy and program issues relating to women's substance and abuse and mental health service needs at