formal presentations should notify the contact person before December 1, 1996, to 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. The committee will consider a premarket approval application (PMA) for a device which calculates a composite index from currently available serum-based clinical laboratory tests to provide additional information, which can assist in identifying osteopenia in women with three or more National Osteoporosis Foundation Risk Factors.

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

Closed presentation of data. The sponsor of the PMA will present to the committee trade secret and/or confidential information. 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 the meeting(s) 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, 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 transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, 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 (a)(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: November 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–29830 Filed 11–21–96; 8:45 am]

BILLING CODE 4160–01–M

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings 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.

MEETINGS: The following advisory committee meetings are announced:

Neurological Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. December 3, 1996, 9:30 a.m., Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 800–228–9290 or 301–590–0044 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 Sue Bae, KRA Corp., at 301–495–1591, ext. 227. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 3:30 p.m.; G. Levering Keely, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Neurological Devices Panel, code 12513. 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.

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 November 25, 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. The committee will discuss and vote on a premarket approval application (PMA) for a cranial electrotherapy stimulator for the management of anxiety disorders and short term relief of symptoms of anxiety.

FDA regrets that it was unable to publish this notice 15 days prior to the December 3, 1996, Neurological Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Neurological Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded 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.

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. December 10 and 11, 1996, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, December 10, 1996, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5 p.m.; open public hearing, December 11, 1996, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5 p.m.; Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Endocrinologic and Metabolic Drugs Advisory Committee, code 12536. 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 human drugs for use in endocrine and metabolic disorders.

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 December 4, 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 December 10, 1996, the committee will hear presentations and discuss data submitted regarding new drug application (NDA) 20–656, Nutropin® (somatropin [rDNA origin] for injection, Genentech, Inc.) and NDA 19–640/S–018, Humatrope® (somatropin [rDNA origin] for injection, Eli Lilly and Co.) for the treatment of Turner's Syndrome. On December 11, 1996, the committee will hear presentations and discuss data submitted regarding NDA 20–720, Rezulin™ (troglidizone, Parke Davis Pharmaceutical Research, a Division of Warner-Lambert) and NDA 20–719, Prelay™ (troglidizone, Sankyo U.S.A.) for the treatment of type II diabetes inadequately controlled with insulin therapy.

Drug Abuse Advisory Committee

Date, time, and place. December 12 and 13, 1996, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, December 12, 1996, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5:30 p.m.; open public hearing, December 13, 1996, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5:30 p.m.; Tracy Riley, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Drug Abuse Advisory Committee, code 12535. Please call the hotline for

information concerning any possible changes.

General function of committee. The committee advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

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 November 28, 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 December 12, 1996, the committee will discuss NDA 20–711, bupropion hydrochloride sustained release tablets, Glaxo Wellcome Inc., as an aid for smoking cessation. On December 13, 1996, the committee will discuss NDA 20–724, Nicotrol® Inhaler (nicotine inhalation system), Pharmacia and Upjohn, Inc., as an aid for smoking cessation.

Oncologic Drugs Advisory Committee

Date, time, and place. December 16, 1996, 8:30 a.m., DoubleTree Hotel, Plazas II and III, 1750 Rockville Pike, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 1 p.m.; open public hearing, 1 p.m. to 1:30 p.m., unless public participation does not last that long; open committee discussion, 1:30 p.m. to 4:30 p.m.; Jannette O'Neill-Gonzalez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Oncologic Drugs Advisory Committee, code 12542. 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 human drugs for use in the treatment of cancer.

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 December 2, 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. The committee will discuss: (1) NDA 20–726 Femara™ Tablets (letrozole, CGS 20267, Ciba-Geigy Corp.), for the treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, following antiestrogen therapy; and (2) product license application (PLA) 92–0306 TICE® (BCG Vaccine, Organon Teknika Corp.), for intravesical installation for prophylaxis against recurrent papillary carcinoma of the urinary bladder.

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

Date, time, and place. December 16 and 17, 1996, 8:30 a.m., Holiday Inn—Bethesda, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, December 16, 1996, 8:30 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 5 p.m.; open public hearing, December 17, 1996, 8:30 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 5 p.m.; Robert L. Sherman or Stephanie A. Mason, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2294, 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 the general issues pending before the subcommittee. Those desiring to make formal presentations should notify the contact person before December 1, 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 December 16, 1996, the subcommittee will discuss xylitol, C31G–Therasol, and the effectiveness of menthol, thymol, methyl salicylate, and eucalyptol. On December 17, 1996, the subcommittee will discuss microdent, and continue its discussion of sodium lauryl sulfate. In addition, the subcommittee will continue its discussion and vote on cetylpyridinium chloride, stannous fluoride, hydrogen peroxide, and sodium bicarbonate. If necessary, the subcommittee will continue its discussion of the effectiveness of menthol, thymol, methyl salicylate, and eucalyptol.

Subcommittee Meeting of the Anesthetic and Life Support Drugs Advisory Committee

Date, time, and place. December 18, 1996, 8:30 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Anesthetic and Life Support Drugs Advisory Committee, code 12529. 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 human drugs for use in the field of anesthesiology and surgery.

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 December 4, 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. The committee will discuss labeling for NDA 18–654, Versed® (midazolam HC1), Hoffmann La-Roche, for pediatric sedation.

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 the meeting(s) 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, 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 transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, 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 (a)(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: November 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–29831 Filed 11–21–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–R–190, HCFA–R–96]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Hospital Standard for Potentially HIV Infectious Blood and Blood Products, 42 CFR 482.27; *Form No.:* HCFA–R–190; *Use:* Hospitals must establish policies/procedures and document patient notification efforts if they have administered potentially HIV infectious blood and blood products.

Frequency: On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 16; *Total Annual Responses:* 16; *Total Annual Hours Requested:* 16.

2. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Emergency and Foreign Hospital Services—Beneficiary Statement In Canadian Travel Claims and Supporting Regulation 42 CFR 424.123; *Form No.:* HCFA–R–96; *Use:* This form is completed by beneficiaries, representative, or assignees to support claims for payments for Medicare covered emergency services provided in Canada. 42 CFR 424.123 is the regulation supporting this collection of information; *Frequency:* On occasion; *Affected Public:* Individuals or households; *Number of Respondents:* 1,100; *Total Annual Responses:* 1,100; *Total Annual Hours:* 275.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed