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:

Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. March 6, 1997, 8:30 a.m., and March 7, 1997, 9 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 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 Soo Bae, KRA Corp., 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, March 6, 1997, 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 2 p.m.; closed presentation of data, 2 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 5:30 p.m.; open public hearing, March 7, 1997, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 2 p.m.; William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–1289, or Jodi H. Nashman, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Orthopedic and Rehabilitation Devices Panel, code 12521. 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 March 3, 1997, 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 March 6, 1997, at the request of, and in conjunction with the Center for Biologics Evaluation and Research, the committee will discuss CARTICEL (autologous chondrocytes manipulated ex-vivo for structural repair, Genzyme Corp.) intended for treatment and repair of clinically significant, articular cartilage defects in the knee. On March 7, 1997, the committee will have a general discussion of study design and efficacy endpoints for clinical trials utilizing bone void fillers.

Closed presentation of data. On March 6, 1997, the sponsor will present to the committee trade secret and/or confidential commercial information relevant to the pending biologics licensing application (BLA). This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the March 6 and 7, 1997, Orthopedic and Rehabilitation 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 Orthopedic and Rehabilitation Devices Panel 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.

Neurological Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. March 14, 1997, 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 Soo Bae, KRA Corp., 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 10:45 a.m., unless public participation does not last that long; open committee discussion, 10:45 a.m. to 3:30 p.m.; closed committee deliberations, 3:30 p.m. to 4:30 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 March 3, 1997, 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 for a deep brain stimulator for the treatment of tremor due to Parkinson's disease and Essential Tremor.

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)).

FDA regrets that it was unable to publish this notice 15 days prior to the March 14, 1997, 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 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.

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. March 20 and 21, 1997, 8 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301– 948–8900 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 Christie Wyatt, KRA Corp., 301–495–1591, ext. 267. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, March 20, 1997, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 9 a.m; closed presentation of data, 9 a.m. to 9:30 a.m.; open committee discussion, 9:30 a.m. to 1:30 p.m.; open public hearing, 1:30 p.m. to 2:30 p.m., unless public participation does not last that long; open committee discussion, 2:30 p.m. to 6 p.m.; open public hearing, March 21, 1997, 8 a.m. to 9:15 a.m., unless public participation does not last that long; open committee discussion, 9:15 a.m. to 6 p.m.; Sharon K. Lappalainen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Clinical Chemistry and Clinical Toxicology Devices Panel, code 12514. 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.

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 March 7, 1997, 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. The Docket will remain open until April 3, 1997, to allow written comment from the public.

Open committee discussion. On March 20, 1997, the committee will discuss a premarket notification submission, 510(k), for an over-the-counter device for measuring fructosamine. On March 20 and 21, 1997, the committee will discuss self-monitoring and management by diabetic patients including noninvasive and invasive self-monitoring blood glucose (SMBG) systems, glucose meters and test strips. The invasive systems have revolutionized modern diabetic management. Improvements in technology and increased understanding of the benefits of tight control have been substantial during the past few years. FDA is interested in identifying mechanisms to help minimize problems associated with SMBG systems. The goal of the meeting is to solicit information and suggestions from the FDA advisory panel, professional organizations, industry, and consumers that will help: (1) Identify how patients are currently being managed; (2) determine what goals are appropriate for different groups of patients and different treatment regimens; (3) determine what device performance is needed for support of these goals; (4) discuss current technology and its performance capabilities and limitations; and (5) identify areas in which the agency, professional groups, patients, and manufacturers can work together to help achieve the various goals of glucose monitoring and contribute to increased quality patient outcomes.

Invasive SMBG systems are used by individuals to monitor their own blood glucose levels. These devices allow individuals to monitor their status on a daily basis and, if necessary, modify therapy to obtain near normal glucose homeostasis. The use of SMBG systems has, therefore, become a cornerstone for modern diabetic therapy of significant importance to many of the 13 million diabetics in the United States. Reports in the medical literature have suggested that meter and strip performance claims made by manufacturers based on premarket testing may not reflect actual use by consumers. Topics of discussion will include:

(1) Improvements which can be made in the premarket review of these products including changes, if warranted, in review criteria and their application;

(2) Identification of realistic expectations for the physician and user of these devices based on current technology, and determination of testing needed to assure product quality. Discussion will include consideration of both existing technical limitations and the potentials for changes in glucose measuring technology in the future;

(3) Improvements which could be made in premarket product testing to provide a more realistic evaluation of actual performance in the field;

(4) Possible improvements in the labeling of these devices to better reflect the expected performance in the home setting;

(5) Steps that could be taken to improve the use of quality control measures in the home setting; and

(6) Other mechanisms available to FDA or other organizations to improve the practice of blood glucose monitoring in the home.

(7) Improvements that could be made to FDA's existing guidance document entitled ''Review Criteria for Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology''—Draft 2/14/96. This guidance document is available through the Division of Small Manufacturer's Assistance (DSMA) at 301–443–6597, its toll free number 800–638–2041, or through DSMA Facts on Demand at 800–899–0381, DSMA Shelf Number 604.

FDA welcomes other input that will contribute to minimizing SMBG related problems.

Closed presentation of data. On March 20, 1997, the sponsor may present to the committee trade secret and/or confidential commercial information regarding the premarket notification submission. 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: February 25, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

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Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Application for Certification as a Federally Qualified Health Center (FQHC) (OMB No. 0915–0142); Extension and Revision

The Federally Qualified Health Center (FQHC) Look-Alike application package (OMB No. 0915–0142) was developed to certify entities as FQHC providers under Medicaid and Medicare. FQHCs receive