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:

Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. January 13, 1997, 9:30 a.m., and January 14, 1997, 9 a.m., Holiday Inn—Gaithersburg, Walker and Whetstone Rooms, 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 or 1–800–465–4329 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, January 13, 1997, 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 1:30 p.m.; closed committee deliberations, 1:30 p.m. to 5:30 p.m.; open public hearing, January 14, 1997, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ophthalmic Devices Panel, code 12396. 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 January 6, 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 January 13, 1997, the committee will discuss general issues relating to a premarket approval application (PMA) for a retinal tamponade used for the treatment of complicated retinal detachments. On January 14, 1997, the committee will discuss general issues relating to a PMA supplement for an excimer laser for photorefractive keratectomy to correct low to moderate myopia with astigmatism.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information relevant to investigational device exemption applications and PMA's for vitreo-retinal, surgical and diagnostic devices, intraocular and corneal implants, and contact lenses. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. January 16, 1997, 8 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 Alice Hall Hayes, KRA Corp. at 301–495–1591, ext. 223. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Closed committee deliberations, 8 a.m. to 9 a.m.; open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 6 p.m.; Mary J. Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area) Gastroenterology and Urology Devices Panel, code 12523. 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 January 9, 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 hear a presentation on the revisions made in the Draft Guidance on Penile Rigidity Implants (November 1996). The committee will discuss general issues related to a PMA for a metallic mesh stent intended to relieve prostatic obstruction secondary to benign prostatic hyperplasia (BPH) or bladder neck contracture.

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

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. January 30, 1997, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open committee discussion, 8 a.m. to 1:30 p.m.; closed committee deliberations, 1:30 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 4:30 p.m.; open public hearing, 4:30 p.m. to 5:30 p.m., unless public participation does not last that long; Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388. 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 vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

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 23, 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 the influenza virus vaccine formulation for 1997–1998. The committee will also hear briefings on a research program in the Division of Bacterial Products and on recent activities in the Center for Biologics Evaluation and Research.

Closed committee deliberations. The committee will review data of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(6)).

Biological Response Modifiers Advisory Committee

Date, time, and place. January 30, 1997, 3 p.m., Rockwall 1 Bldg., conference room 4108, fourth floor, 11400 Rockville Pike, Rockville, MD.

Type of meeting and contact person. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open public hearing, 3 p.m. to 4 p.m., unless public participation does not last that long; open committee discussion, 4 p.m. to 4:30 p.m.; closed committee deliberations, 4:30 p.m. to 5:30 p.m.; William Freas, Sheila D. Langford, or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Biological Response Modifiers Advisory Committee, code 12388. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases.

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 23, 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 the intramural research program for the Laboratory of Cell Biology, Division of Cytokine Biology.

Closed committee deliberations. The committee will discuss the intramural scientific program. This portion of the meeting will be closed to prevent disclosure of personal information concerning individuals associated with the research program, disclosure of which would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

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: December 16, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

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BILLING CODE 4160–01–F

Memorandum of Understanding Between the Food and Drug Administration and the Republic of Belarus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Republic of Belarus. The purpose of the MOU is to exchange information on drugs and biological products and to facilitate the development of the Belarus health care sector by establishing in Belarus a streamlined registration procedure for U.S. drugs and biological products.

DATES: The agreement became effective March 25, 1996.

FOR FURTHER INFORMATION CONTACT: Bradford W. Williams, Office of Compliance, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0165.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the Federal Register, the agency is publishing notice of this memorandum of understanding.

Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

224–96–4004

Memorandum of Understanding Between the Food and Drug Administration of the Department of Health and Human Services of the United States of America and the Ministry of Health of the Republic of Belarus on Cooperation and Information Exchange for Facilitating the Introduction of Drugs and Biological Products into the Republic of Belarus

The Food and Drug Administration (FDA), of the Department of Health and Human Services of the United States of America, on the one hand; and the Ministry of Health of the Republic of Belarus, on the other hand, hereinafter referred to as the parties,

Guided by principles recorded in the Agreement between the Government of the United States of America and the Government of the Republic of Belarus on Science and Technology Cooperation, signed in Minsk on January 14, 1994, and

Strengthening the bonds of friendship between the parties, Have reached an understanding on matters of cooperation:

I

The goals of the parties are:

1. To exchange information on drugs and biological products and on requirements applicable to them (including standardization, registration, quality control, and side effects), and prompt exchange of information on the removal of drugs and biological products from the market or restrictions on their use.
2. To facilitate the development of the Belarusian health care sector by establishing in Belarus a streamlined registration procedure for United States drugs and biological products that are manufactured and marketed in the United States under the jurisdiction of the FDA as provided in the Annexes to this Memorandum of Understanding. The Belarusian party should use the streamlined procedure for such products.

The parties confirm that it would be mutually beneficial for the parties to work together to streamline the process for registering in Belarus drugs and biological products when these products are permitted by the FDA to be marketed in the United States. The effect of the parties joint endeavors under this Memorandum of Understanding should be to extend to Belarusian users access to the same United States drugs and biological products as are available to United States users of such products, which possess a high degree of safety, effectiveness, and quality .

II

This Memorandum of Understanding covers drugs and biological products manufactured and marketed in the United States under the jurisdiction of the FDA including:

1. Drugs: articles that meet the definition of a drug under the United States Federal