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Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

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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.

MEETINGS: The following advisory committee meetings are announced:

Joint: Meeting of the Arthritis Advisory Committee and OTC Drugs Advisory Committee

Date, time, and place. June 1 and 2, 1993, 8:30 a.m., conference rooms D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, June 1, 1993, 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.; closed committee deliberations, June 2, 1993, 8:30 a.m. to 5 p.m.; Isaac F. Roubein, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3741.

General function of the committees. The Arthritis Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions. The OTC Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and 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 May 21, 1993, 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 June 1, 1993, the committee

will discuss: (1) Juvenile rheumatoid arthritis (JRA) guidelines, and (2) the new drug application (NDA) for Naprosyn(R) (Naproxen) NDA 20-204, Syntex Corp., switch from prescription to over-the-counter (OTC).

Closed committee deliberations. On June 2, 1993, the committee will review trade secret and/or confidential commercial information relevant to pending NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. June 3 and 4, 1993, 9 a.m., National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Parking in the Clinical Center Visitor area is reserved for clinical center patients and their visitors. If you must drive, please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every 8 minutes during rush hour and every 15 minutes at other times.

Type of meeting and contact person. Open public hearing, June 3, 1993, 9 a.m to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 5 p.m.; open committee discussion, June 4, 1993, 9 a.m. to 1 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419-259-6211 or Valerie M. Mealy, Advisors and Consultants Staff, 301-443-4695.

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 cardiovascular and renal 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 May 20, 1993, 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 June 3, 1993, the committee will discuss possible labeling revisions for organic nitrates. On June 4, 1993, the committee will discuss possible labeling revisions for quinidine.

Closed committee deliberations. The committee will review trade secret and/or confidential commercial information relevant to pending investigational new drugs (IND's) and NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Drug Abuse Advisory Committee

Date, time, and place. June 7, 1993, 9 a.m., and June 8, 1993, 8:30 a.m., conference rooms D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, June 7, 1993, 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.; closed committee deliberations, June 8, 1993, 8:30 a.m. to 5 p.m.; Isaac F. Roubein, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, 301-443-3741.

General function of the 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 May 28, 1993, 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 June 7, 1993, the committee will discuss: (1) The results of the levo-alpha-acetylmethadol hydrochloride (LAAM) usage trial, (2) the adequacy of the proposed labeling, (3) the safety and efficacy of LAAM under the conditions of use recommended in the proposed labelling for the treatment of opiate addiction, and (4) completeness of the application and the possible need for any phase IV studies.

Closed committee deliberations. On June 8, 1993, the committee will review trade secret and/or confidential commercial information relevant to a pending NDA. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Blood Products Advisory Committee

Date, time, and place. June 28, 1993, 8 a.m. and June 29, 1993, 8:30 a.m., Holiday Inn Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, June 28, 1993, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 6 p.m; open committee discussion, June 29, 1993, 8:30 a.m. to 3 p.m.; closed committee discussion, 3 p.m. to 4 p.m.; Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-300), Food and Drug Administration, 1401 Rockville Pike, Bethesda, MD 20852, 301-227-6700.

General function of the committee. The committee reviews and evaluates data on the safety, effectiveness, and appropriate use of blood-based biological products and devices 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 June 21, 1993, 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 June 28, 1993, the committee will participate in a public workshop entitled: The Safety of Plasma Donation and make recommendations. The issues to be discussed are as follows: (1) The effect of plasmapheresis on donor health; (2) the quality of plasma and plasma derivatives; and (3) ethical issues in remuneration of plasma donors. On June 29, 1993, the committee will discuss and provide comments on the following

topics: (1) Donor suitability criteria relative to exposure to malaria, (2) the public health issue of Idiopathic CD4+ T-Lymphocytopenia (ICL), and (3) the report of the scientific site visit review for the Laboratory of Hemastasis, Division of Hematology, Office of Blood and Blood Research, Center for Biologics Evaluation and Research.

Closed committee deliberations. The committee will discuss information of a personal nature where disclosure would constitute 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)).

OTC Drugs Advisory Committee

Date, time and place. June 28 and 29, 1993, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, June 28, 1993, 8 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 p.m.; closed committee deliberations, 4 p.m. to 5 p.m.; open committee discussion, June 29, 1993, 8 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 5 p.m.; Mae Brooks or Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and 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 June 21, 1993, 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 the morning of June 28, 1993, the committee will discuss labeling for OTC drug products containing doxylamine succinate to alert consumers that studies have shown an increase in the development of tumors in laboratory animals administered this ingredient. The agency summarized these studies in the final monograph for OTC antihistamine drug products that published in the Federal Register of December 9, 1992, (57 FR 58356). The Pulmonary-Allergy Drugs Advisory Committee has recommended that doxylamine remain OTC but that there be some warning to consumers that the animal tumorigenicity data exist. The committee will limit its discussion to potential OTC drug products labeling to alert consumers appropriately of these findings. The committee's recommendations will be considered by the agency in making a final decision on doxylamine in OTC antihistamine drug products, which will be published in the Federal Register at a later date. The committee's recommendations will also apply to doxylamine used in OTC nighttime sleep-aid drug products, marketed under approved applications.

On the afternoon of June 28, 1993, the committee will have an informational briefing on the regulation of advertising of

OTC drug products by the Federal Trade Commission. This briefing is intended to inform the committee how OTC drug products are regulated and is not directly related to any issues currently under consideration by the committee or the agency.

On June 29, 1993, the committee will discuss the relationship between alcohol and acetaminophen-induced liver toxicity. The agency's evaluation of data relating to the role of microsomal enzyme inducers, including alcohol, in acetaminophen-induced liver damage was discussed in comment 27 of the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products, published in the Federal Register of November 16, 1988 (53 FR 46204). Additional new data submitted since that time will be considered by the committee members as they discuss whether the totality of the information warrants label revisions concerning the use of OTC dosages of acetaminophen with alcohol. The committee's recommendations will be considered by the agency in its preparation of the final monograph for OTC internal analgesic drug products.

Closed committee deliberations. On June 28, 1993, the committee will discuss trade secret and/or confidential commercial information relevant to pending IND's. 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, with the concurrence of the Chief Counsel, 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, notably deliberative session 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: May 10, 1993