

Dated: February 14, 1995.

**Linda A. Suydam,**

*Interim Deputy Commissioner for Operations.*

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#### **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:

#### **Allergenic Products Advisory Committee**

*Date, time, and place.* March 10, 1995, 9 a.m., Woodmont Office Complex I, conference room 400-N, 1401 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 committee discussion on review of research, 9 a.m. to 10 a.m.; closed committee deliberations, 10 a.m. to 11:05 a.m.; open public hearing, 11:05 a.m. to 12:05 p.m., unless public participation does not last that long; Jack Gertzog or Sandy Salins, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike,

Bethesda, MD 20852, 301-827-0314, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Allergenic Products Advisory Committee, code 12388.

*General function of the committee.*

The committee reviews and evaluates data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human disease.

*Agenda—Open public hearing.*

Interested persons requesting to present data, information, or views, orally or in writing, on issues pending before the committee, should communicate with the contact person.

*Open committee discussion.* The committee will discuss the intramural scientific program of the Laboratory of Immunobiochemistry and the clinical research programs of individuals in the Division of Allergenic Products and Parasitology.

*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)).

#### **Arthritis Advisory Committee**

*Date, time, and place.* March 27, 1995, 8:30 a.m., Holiday Inn—Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing a joint meeting on March 28, 1995, with the Nonprescription Drugs Advisory Committee.

*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 12:30 p.m.; closed committee deliberations, 12:30 p.m. to 5:30 p.m.; Isaac F. Roubein, Center for Drug Evaluation and Research (HFD-9), 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), Arthritis Advisory Committee, code 12532.

*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 arthritic conditions.

*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 16, 1995, 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 new drug application (NDA) 18-922, Lodine® (etodolac) Wyeth-Ayerst Laboratories, which is proposed for the treatment of rheumatoid arthritis.

*Closed committee deliberations.* The committee will review trade secret and/or confidential commercial information relevant to pending investigational new drugs. 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: February 14, 1995.

**Linda A. Suydam,**

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## **National Institutes of Health**

### **Technology Assessment Conference on Gaucher Disease: Current Issues in Diagnosis and Treatment**

Notice is hereby given of the NIH Technology Assessment Conference on "Gaucher Disease: Current Issues in Diagnosis and Treatment," which will be held February 27-March 1, 1995, in the Masur Auditorium of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8:30 a.m. on February 27 and 28 and at 9 a.m. on March 1.

Gaucher disease, the inherited deficiency of the enzyme glucocerebrosidase, is the most common lysosomal storage disease and the most frequently inherited disorder in the Ashkenazic Jewish population. In the past decade there has been much progress both in our understanding of the molecular biology of the disease and the ability to treat Gaucher patients. However, many issues regarding diagnosis, population screening, and therapy for Gaucher patients do not have clear consensus. Gaucher disease is characterized by a remarkable degree of clinical heterogeneity, ranging from severely affected infants to totally asymptomatic adults. Patients with Gaucher disease have been classified into three major types on the basis of clinical signs and symptoms: Type 1—non-neuropathic; type 2—acute neuropathic; and type 3—subacute neuropathic.

All types of Gaucher disease result from the deficiency of the same enzyme, glucocerebrosidase, and the diagnosis can be made by measurement of enzyme activity obtained from a tube of blood. The most striking difference between the types is the presence of neurologic manifestations and the rate of progression. Even within the different types there is not a unique clinical presentation. Some patients with type 1 Gaucher disease, which is by far the most common type, may display anemia, low platelets, massively enlarged livers and spleens, and extensive skeletal disease, while others have no symptoms and have been recognized only during screening or evaluation for other diseases.

The gene for glucocerebrosidase on chromosome 1q21 has been characterized and sequenced. Multiple mutations have been identified in the glucocerebrosidase gene in patients' DNA, several of which are encountered frequently. While some patients with similar clinical courses share the same genotype, there are other examples where patients with the same DNA mutations have very different clinical manifestations. It is still not clear to what extent a person's phenotype or prognosis can be accurately predicted on the basis of current DNA mutation analysis. Furthermore, while the availability of molecular techniques has made possible early prenatal diagnosis, heterozygote detection and population screening for Gaucher disease, the advisability and usefulness of these techniques remains unsolved.

Gaucher disease has been traditionally managed by supportive therapy including total and partial splenectomy, transfusions, and