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,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–4195 Filed 2–16–95; 8:45 am]

BILLING CODE 4160–01–F

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

orthopedic procedures. Bone marrow transplantation has also been successfully performed. More recently enzyme replacement therapy has become available using a mannose terminated form human glucocerebrosidase. This therapy, often costing $100,000 to $300,000 per adult patient annually, has effectively improved biochemical and hematologic manifestations of this disorder in many patients and has reversed hepatosplenomegaly. The optimal dosing for this preparation is still under investigation. Also, other novel strategies for enzyme therapy and gene therapy for Gaucher disease are being actively pursued.

The purpose of this Technology Assessment Conference is to evaluate current concepts concerning diagnosis, genetic counseling, and management of Gaucher disease. The conference will bring together epidemiologists, geneticists, pediatricians, neurologists, obstetricians, orthopedists, hematologists, genetic counselors, clinical pathologists, others involved in health care delivery, as well as representatives of the public to review available data and make recommendations regarding population screening, genetic counseling, and current patient management as well as for future research.

After 1-½ days of presentations and audience discussion, an independent, non-Federal panel will weigh the scientific evidence and write a draft statement that it will present to the audience on the third day. The statement will address the following key questions:

What is the natural history of Gaucher disease and what is the appropriate technology to assess the severity and to predict the progression of this disorder?

What are the roles of current molecular and enzymatic assays for ascertaining affected individuals and carriers in various populations?

What are the indications for treatment of patients with Gaucher disease and what are the appropriate modes of therapy?

What are the goals for and consequences of treatment and how can the therapeutic interventions be assessed?

Under what circumstances could genotype/phenotype correlations be used for patient care and counseling?

What are the appropriate directions for future research?

The primary sponsors for this conference are the National Institute of Mental Health and the NIH Office of Medical Applications of Research. The conference is cosponsored by the National Institute of Child Health and Human Development, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Neurological Disorders and Stroke, the National Center for Research Resources, and the National Center for Human Genome Research.

Advance information on the conference program and conference registration materials may be obtained from: Debra DeBose, Technical Resources International, Inc., 3202 Tower Oaks Blvd., Suite 200, Rockville, Maryland 20852, (301) 770–3153.

The technology assessment statement will be submitted for publication in professional journals and other publications. In addition, the statement will be available beginning March 1, 1995 from the NIH Consensus Program Information Service, P.O. Box 2577, Kensington, Maryland 20891, phone 1–800–NIH–OMAR (1–800–644–6627).

Dated: February 10, 1995.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 95–3991 Filed 2–16–95; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meetings of the following Heart, Lung, and Blood Special Emphasis Panels.

These meetings will be open to the public to provide concept review of proposed contract or grant solicitations.

Individuals who plan to attend and need special assistance, such as a sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

Name of Panel: NHLBI SEP on Pulmonary Vascular Biology.

Dates of Meeting: March 9, 1995.

Time of Meeting: 8:00 a.m.

Place of Meeting: National Institutes of Health, Building 31C, Conference Room 8, Bethesda, Maryland.

Agenda: The panel will review the current status of research in the designated areas, identify gaps and make recommendations regarding opportunities and priorities for future contract or grant solicitations.

Contact Person: Dorothy B. Gail, Ph.D., 5333 Westbard Avenue, Room 6407, Bethesda, Maryland 20892, (301) 549–7428.

Name of Panel: NHLBI SEP on TB/AIDS.

Dates of Meeting: March 21, 1995.

Time of Meeting: 8:30 a.m.

Place of Meeting: National Institutes of Health, Natcher, Building 45, Conference Room C–1, Bethesda, Maryland 20892.

Agenda: The panel will review the current status of research in the designated areas, identify gaps and make recommendations regarding opportunities and priorities for future contract or grant solicitations.

Contact Person: Hannah H. Peavy, M.D., 5333 Westbard Avenue, Room 6A09, Bethesda, Maryland 20892 (301) 594–7428.

Name of Panel: NHLBI SEP on Critical Care.

Dates of Meeting: March 28, 1995.

Time of Meeting: 8:30 a.m.

Place of Meeting: National Institutes of Health, Natcher, Building 45, Conference Room C–1, Bethesda, Maryland 20892.

Agenda: The panel will review the current status of research in the designated areas, identify gaps and make recommendations regarding opportunities and priorities for future contract or grant solicitations.

Contact Person: Carol H. Bosken, M.D., 5333 Westbard Avenue, Room 6A07, Bethesda, Maryland 20892, (301) 549–7428.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: February 9, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–3988 Filed 2–16–95; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Notice of a Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meeting:

Name of SEP: Demonstration and Education Research Applications.

Date: March 14–15, 1995.

Time: 9:00 a.m.

Place: Stouffer Concourse Hotel, Arlington, VA.

Contact Person: Dr. Louise Corman, 5333 Westbard Avenue, Room 548, Bethesda, MD 20892, (301) 594–7452.

Purpose/Agenda: To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)