pending before an Administrative Law Judge.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 95–16256 Filed 6–30–95; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

White House Conference on Aging

AGENCY: White House Conference on Aging, AoA, HHS.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given, pursuant to Title II of the Older Americans Act Amendments of 1987, Pub. L. 100–175 as amended by Pub. L. 102–375 and Pub. L. 103–171, that the 1995 White House Conference on Aging Business Advisory Committee will meet on Monday, July 17, 1995 from 10:00 AM–noon in the Hubert H. Humphrey Building at 200 Independence Avenue, SW in Washington, DC. Information on the specific room in which the meeting will be held can be obtained by calling the telephone number given below. The meeting of the Committee shall be open to the public.

The proposed agenda includes discussion of how the Committee and the business community can assist with implementation of the resolutions adopted by the Conference delegates. Records shall be kept of all Committee proceedings and shall be available for public inspection at 501 School Street, SW, 8th Floor, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: White House Conference on Aging, 501 School Street, SW, 8th Floor, Washington, DC 20024; telephone (202) 245–7116.

Fernando M. Torres-Gil,

Assistant Secretary for Aging.

[FR Doc. 95–16270 Filed 6–30–95; 8:45 am]

BILLING CODE 4130–02–M

Agency for Health Care Policy and Research

Health Care Policy and Research Special Emphasis Panel Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2) announcement is made of the following special emphasis panel scheduled to meet during the month of August 1995:

Name: Health Care Policy and Research Special Emphasis Panel

Date and Time: August 10, 1995, 8:30 a.m.

Place: Hyatt Regency, One Bethesda Metro Center, Conference Room TBA, Bethesda, MD 20814.

Open August 10, 8:30 a.m. to 9 a.m. Closed for remainder of meeting.

Purpose

This panel is charged with conducting the initial review of grant applications proposing health services research training programs under the National Research Service Awards Program.

Agenda

The open session of the meeting on August 10, from 8:30 a.m. to 9 a.m., will be devoted to a business meeting covering administrative matters. During the closed session, the committee will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), it has been determined that this latter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roaster of members or other relevant information should contact Linda W. Blankenbaker, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594–1438.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: June 26, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95–16253 Filed 6–30–95; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 92N–0371]

New Drug Applications; Refusal to File; Change in Procedures to Include Industry Representatives in Meetings of the Review Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a change in the review process conducted by the Center for Drug Evaluation and Research's (CDER's) Refusal to File (RTF) review committee. The new procedures will permit applicants that have received an RTF to attend the meeting at which the RTF review committee evaluates the RTF imposed on its application. This change, which will be implemented on a trial basis, may enhance understanding of and participation in the RTF review committee process. Additional changes to the procedures may be useful and comments are requested.

DATES: Comments may be submitted at any time.

ADDRESSES: Submit written comments on this change in procedures to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Janet M. Jones, Center for Drug Evaluation and Research (HFD–014), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5445.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 18, 1993 (58 FR 28983), FDA announced the establishment of a standing committee in CDER's to conduct periodic review of the CDER's RTF decisions. The committee was established on a 1-year trial basis. Initially, the committee invited companies to submit requests for review of RTF's that they considered to have been made inappropriately. The RTF review committee consists of senior CDER officials, a senior official from the Center for Biologics Evaluation and Research, and FDA's Chief Mediator and Ombudsman.

CDER created the RTF review committee because it believes that a clear, well-understood, and consistently applied RTF policy may improve substantially the efficiency of the new drug evaluation process. The practice of submitting an incomplete or inadequate application and then providing additional information during an extended review period is inherently inefficient and a waste of agency resources. In addition, it is unfair to those applicants who fulfill their scientific and legal obligations by submitting complete applications to have the review of their applications delayed while other incomplete applications submitted earlier undergo review and repair.

FDA regulations on filing applications, including grounds and procedures for RTF's, are found in § 314.101 (21 CFR 314.101). In the past, some CDER review divisions refused to

file applications only where the deficiencies were extreme while other divisions applied the regulation more broadly. When deciding whether to file an application, CDER exercises discretion, considering in particular whether the application is for a medically important drug. The RTF procedure is used in the context of CDER's effort to promote rapid development and review of applications.

Although an RTF is not a final determination, it is a significant step that delays full review of an application. The applicant who receives an RTF notification may request an informal conference with FDA and thereafter may ask that the application be filed over protest as described under § 314.101(a)(3). CDER believes that an RTF decision is, in general, of benefit to applicants as an early signal that the application has major deficiencies.

When the RTF review began, FDA invited companies to request review of RTF decisions that they wanted FDA to reconsider. As explained in the **Federal Register** of September 21, 1994 (59 FR 48440), in January 1994, the RTF review committee began to meet bimonthly and to review all of the RTF decisions that CDER makes, rather than only some of them, and requests by drug companies were no longer necessary. CDER decided to review all of the RTF decisions because the number of those decisions had decreased over the previous year and because RTF decisions have other effects related to user fees. Under section 736(a)(1)(D) of the Prescription Drug User Fee Act of 1992 (21 U.S.C. 379h(a)(1)(D)), FDA is authorized to retain 25 percent of the total user fee assessed for each NDA that it refuses to file. If the agency incorrectly refuses to file an application, FDA needs to identify and correct the error promptly so that the application may be filed and a review initiated and so that incorrectly retained fees may be returned to the applicant.

To increase the understanding of and participation in this process, the RTF review committee has decided to invite each company whose application has been refused for filing to the committee meeting scheduled to review that RTF decision. The committee usually will review no more than four RTF's per meeting. At the RTF review meeting, the CDER division that made the RTF decision will present to the committee the deficiencies present in the application and will explain the RTF decision. The applicant will not attend this portion of the meeting as the discussion generally involves, among other things, predecisional deliberations and internal management issues. After the division's presentation, the applicant will be invited to give a brief presentation (approximately 10 minutes), and may be asked questions by the committee. For the reasons specified above, the applicant will not remain for the committee deliberations on the appropriateness of the RTF, but will be advised of its decision. The agency also may send followup correspondence to the applicant after the meeting. Because the presentations may deal with confidential commercial information, applicants will not be permitted to be present during presentations made by other companies.

The change in the procedures will be implemented on a trial basis at the next meeting to review RTF decisions. Additional changes to the procedures may be appropriate, and comments are requested.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this change in procedures. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 26, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–16205 Filed 6–30–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Neurological Disorders and Stroke: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Development of a High Performance Gene Expression Mapping Assay System

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) seeks an agreement with a company(ies) which will collaborate on the development of an automated high capacity, high resolution cellular gene mapping assay system for mRNA expression analysis system or genomic fingerprinting.

ADDRESSES: Questions concerning scientific aspects of this opportunity may be addressed to Roland Somogyi, Ph.D., National Institutes of Health, NINDS, 9000 Rockville Pike, Building 36, Room 2C02, Bethesda, MD 20892. Telephone: 301–402–1407, or e-mail: ROLANDS@HELIX.NIH.GOV. Business questions should be addressed to Stephen Finley, Ph.D., National Institutes of Health, NINDS, 9000 Rockville Pike, Building 31, Room 8A46, Bethesda, MD 20892. Telephone: 301–496–4697, or e-mail: SF31W@NIH.GOV.

DATES: Proposals should be received by September 1, 1995.

SUPPLEMENTARY INFORMATION: The Laboratory of Neurophysiology (LNP) studies the cellular function and processes of normal and abnormal nerve cells. The over- and under-expression of genes play critical roles in the control of cellular function, proliferation, and differentiation, and are responsible for a number of neurodegenerative disorders and hyperplasias. The LNP developed a quantitative reverse transcription polymerase chain reaction based protocol which optimizes the identification of over- or under-expression of genes in a cell. A library of primers for over 100 different signaling genes have been successfully used to screen expression patterns in nerve cells.

Current cellular gene expression research is hampered by the time required for sequential analysis of the expressed genes in a cell. There is no fully automated high capacity, high resolution assay system developed for gene expression mapping (GEM).

An assay system which analyzes the expressed genes in cells will provide a new opportunity for exploring how environmental or genetic changes alter the cellular expression of genes. The significance of such a system is that it allows cascade effects of a single event to be analyzed in toto, as contrasted to being limited to the study of the effect on a single gene. This new approach will refine the study of cellular signaling processes and open the field of experimental genetic networks. The study of genetic networks represents a frontier which will provide insight into complex interactions between genes. This is becoming a necessity since many current findings cannot be understood in terms of a single gene acting in isolation.

The LNP would like to collaborate in developing an automated system for the laborious gene expression assay process which incorporates sample preparation, reverse transcription polymerase chain reaction, thermal cycling, and high speed analysis of the final product. The aim of this CRADA is to produce an automated system which breaks through