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

the current technological barriers and ultimately enables the cataloging of the expression levels of all genes in a cell type. The culmination of this CRADA could provide a means to simultaneously screen the mRNA variations in a multitude of cell types or provide a means for the genomic fingerprinting of cellular DNA.

Role of NINDS

1. The LNP will provide its expertise in the quantitative reverse transcription polymerase chain reaction (RTPCR) protocol it developed as well as a custom library of primers for over 100 different genes.
2. Collaborate in designing instrumentation adapted for high volume, high resolution gene expression analysis.
3. Collaborate in the formulation, evaluation, optimization of experimental protocols based on the quantitative RTPCR protocols identified above.

The role and criteria for selection of the successful company(ies) under the CRADA will include, but may not be limited to, the following:

1. Having an established ability to design, manufacture or modify in one or more of the following: Thermocycling devices, capillary electrophoresis devices, automated detection systems (i.e fluorescence or chromophoric) and laboratory robotics.
2. Ability to provide appropriate instrumentation either owned by the company or obtained through third party licensing agreements.
3. Ability to market and sell the final product produced through the collaboration.

Dated: June 16, 1995.

Barbara McGarey,

Deputy Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 95–16233 Filed 6–30–95; 8:45 am]

BILLING CODE 4140–01–P

Meeting of the Panel to Assess the NIH Investment in Research on Gene Therapy

Notice is hereby given that the Panel to Assess the NIH Investment in Research on Gene Therapy, a fact-finding group reporting to the Advisory Committee to the Director (ACD), National Institutes of Health (NIH), will convene two regional meetings to provide the Panel with an opportunity to hear presentations from researchers regarding activities relevant to gene therapy. The first meeting will be held at Building 31C, Conference Room 10, National Institutes of Health, Bethesda, Maryland 20892, on July 13, 1995. The second meeting will be held at the Sir Francis Drake Hotel on Union Square, 450 Powell Street, San Francisco, California 94102, on August 17, 1995. These meetings will begin at approximately 9:30 a.m. and will end at approximately 5 p.m.

The goal of the Panel is to make recommendations to the ACD about the scientific areas that NIH should emphasize and the funding mechanisms that should be employed in order best to advance the development of gene therapy.

Written statements will be accepted and provided to the Panel prior to the meetings. Statements should be sent to Judith H. Greenberg, Ph.D., National Institutes of Health, Natcher Building, Room 2AS.19H, 45 Center Drive MSC 6200, Bethesda, Maryland 20892–6200, or via e-mail at greenbej@gm1.nigms.nih.gov or fax at (301) 480–2228.

Individuals who plan to attend one of the regional meetings and need special assistance, such as sign language interpretation or other special accommodations, should contact the person named below in advance of the meeting.

Attendance may be limited to seat availability. If you plan to attend the meeting as an observer or if you wish additional information, please contact Ms. Janice Ramsden, National Institutes of Health, Shannon Building, Room 235, 1 Center Drive MSC 0159, Bethesda, Maryland 20892–0159, telephone (301) 496–0959, fax (301) 496–7451, e-mail address ramsdenj@aow.nih.gov by July 7 for the Bethesda meeting and August 11 for the San Francisco meeting.

Dated: June 22, 1995.

Ruth L. Kirschstein,

Deputy Director, National Institutes of Health.

[FR Doc. 95–16234 Filed 6–30–95; 8:45 am]

BILLING CODE 4140–01–P

National Institute on Deafness and Other Communication Disorders; 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 meeting:

Name of Committee: Ad Hoc Hearing and Hearing Impairment Subcommittee of the National Deafness and Other Communication Disorders Advisory Council.

Date: July 20, 1995.

Time: 1–4 p.m. (telephone conference).

Place: National Institutes of Health, Building, 31C, Conference Room 9, 9000 Rockville Pike, Bethesda, Maryland 20892.

Contact Person: Mr. Baldwin Wong, Program Analyst, NIDCD/PPHRB, 31 Center Drive, MSC 2320, Room 3C–35, Bethesda, Maryland 20892–2320, (301) 496–7243.

Purpose: To recommend individuals to serve on a scientific panel to update the hearing and hearing impairment section of the Research Plan.

The meeting will be closed in accordance with the provisions set forth in sec. 552b)(c)(6), Title 5, U.S.C. These discussions could reveal personal information concerning these individuals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.173, Biological Research Related to Deafness and Communication Disorders)

Dated: June 26, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–16231 Filed 6–30–95; 8:45 am]

BILLING CODE 4140–01–M

Division of Research Grants; Closed Meetings

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 Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Behavioral and Neurosciences.

Date: July 13, 1995.

Time: 12:00 noon.

Place: Embassy Suites Hotel, Washington, DC.

Contact Person: Dr. Anita Sostek, Scientific Review Administrator, 6701 Rockledge Drive, Room 5202, Bethesda, MD 20892, (301) 435–1260.

Name of SEP: Multidisciplinary Sciences.

Date: July 14, 1995.

Time: 1:00 p.m.

Place: NIH, Rockledge II, Room 5210, Telephone Conference.

Contact Person: Dr. Nadarajen Vydelingum, Scientific Review Admin. 6701 Rockledge Drive, Room 5210, Bethesda, MD 20892, (301) 435–1176.

Name of SEP: Microbiological and Immunological Sciences.

Date: July 17, 1995.

Time: 1:00 p.m.

Place: NIH, Rockledge II, Room 4200, Telephone Conference.

Contact Person: Dr. Gil Meir, Scientific Review Administrator, 6701 Rockledge Drive, Room 4200, Bethesda, MD 20897, (301) 435–1219.

Name of SEP: Microbiological and Immunological Sciences.

Date: July 18, 1995.

Time: 10:00 a.m.

Place: NIH, Rockledge II, Room 4180, Telephone Conference.

Contact Person: Dr. Tim Henry, Scientific Review Administrator, 6701 Rockledge Drive,