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: March 16, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–7069 Filed 3–17–95; 3:46 pm]

BILLING CODE 4160–01–F

Health Care Financing Administration

Office of Research and Demonstrations; Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA), (**Federal Register**, Vol. 59, No. 60, pp. 14642–43, dated Tuesday, March 29, 1994) is amended to reflect various changes resulting from the streamlining and reorganization of the Office of Research and Demonstrations (ORD).

These changes abolish the current ORD substructure which consists of three subordinate offices and one staff, and establish a new substructure which consists of four subordinate offices and two subordinate staffs. These changes will realign all current ORD functions into the following activity areas: information dissemination; financial, administrative, and procurement support; state health reform demonstrations; payment, delivery, and financing research and demonstrations; beneficiary related research and demonstrations; and ORD program support activities.

The specific changes to Part F are:

- Section F.10.C.3.a, through Section F.10.C.3.c.(2) is deleted in its entirety and replaced by the following revised functional statements. The new sections F.10.C.3.a through F.10.C.3.f.(2) read as follows:

A. Dissemination Staff (FKB–2)

- Produces and distributes ORD publications, such as the Health Care Financing Review, Status Report, Publications Catalog, and Reports to Congress.
- Coordinates ORD's input for the annual HCFA Report to Congress.
- Markets materials, including electronically produced data and publications to consumers, customers and other individuals or organizations.
- Develops new dissemination strategies that encourage the adoption and diffusion of innovations in health care financing and delivery.
- Manages internal and external inquiries.
- Provides conference support.
- Provides technical and editorial support services.
- Coordinates with the Government Printing Office and the National Technical Information Service.
- Maintains resource material for internal use.
- Develops and disseminates internal communications and operational procedures.
- Reviews, coordinates and serves as liaison for administrative correspondence.

B. Financial, Administrative and Procurement Staff (FKB–3)

- Plans, directs and implements a comprehensive office-wide human resources and employee development program.
- Coordinates ORD's section of the HCFA strategic plan.
- Coordinates the Federal Managers Financial Integrity Act.
- Plans, directs and implements office-wide facilities and property management programs.
- Plans, directs and implements comprehensive office-wide budget and financial management programs.
- Coordinates grants, contracts, cooperative agreements and waiver activities.
- Plans and develops ORD's Acquisition Planning Document.
- Develops and implements the ORD Waiver Compendium.
- Manages Freedom of Information and Privacy Act issues.

C. Office of State Health Reform Demonstrations (FKB4)

- Conducts research, demonstrations and evaluations to support the development and implementation of State health and welfare reform demonstrations.
- In partnership with other HCFA bureaus and DHHS offices, directs the

Department's response to all aspects of the State's proposal and any proposed changes to ongoing demonstration activities.

- Monitors ongoing operations of the State's demonstration in partnership with other HCFA bureaus and regional offices.
- Funds technical assistance to States in the implementation and evaluation of these programs.

D. Office of Payment and Delivery Research and Demonstrations (FKB5)

- Directs intramural and extramural research, demonstrations and evaluations of managed care and other delivery systems including studies supporting the development of associated payment systems and the development of infrastructure in underserved areas.
- Directs intramural and extramural research, demonstrations and evaluations of broad reforms of the Medicare and Medicaid programs, studies to evaluate the impact of proposals for reform of the health care system and studies of health care financing systems.
- Directs intramural and extramural research, demonstrations and evaluations to support the development, implementation and refinement of payment policies including the extension of existing payment systems to excluded providers and other payers.
- Directs and performs analyses to assist in delivery and systems reform and payment policy development.

D.(1) Division of Delivery Systems and Financing (FKB51)

- Conducts intramural and extramural research, demonstrations and evaluations of managed care and other delivery systems including the development of infrastructure in underserved areas (rural/inner-city areas).
- Conducts intramural and extramural research, demonstrations and evaluations to support the development and implementation of payment systems associated with delivery and systems reform.
- Conducts intramural and extramural research, demonstrations and evaluations to develop and implement patient and other classification systems, including risk adjustment methodologies, for new delivery and payment systems.
- Conducts intramural and extramural research, demonstrations and evaluations of broad reforms of the Medicare and Medicaid programs.
- Conducts intramural and extramural research studies to evaluate the impact of proposals for reform of the health care system.
- Conducts intramural and extramural research, demonstrations and evaluations of health care financing issues.
- Performs analyses to assist in delivery and systems reform policy development.

D.(2) Division of Payment Systems (FKB52)

- Conducts intramural and extramural research, demonstrations and evaluations to support the development, implementation and refinement of payment policy for hospitals, physicians, drugs, outpatient facilities, skilled nursing facilities, home health agencies and other providers.
- Conducts intramural and extramural research, demonstrations and evaluations to support the extension of payment systems to excluded providers and to other payers.
- Conducts intramural and extramural research, demonstrations and evaluations to develop and implement patient and other classifications for payment systems.
- Conducts intramural and extramural research studies of the impact of payment systems on providers and other payers.
- Conducts intramural and extramural research studies on developments/changes in the health care sector and evaluate the implications for payment policy.
- Assists in the development and implementation of payment policies to expand access and develop infrastructure in underserved areas (rural/inner-city areas).
- Performs analyses to assist in payment policy development.

E. Office of Beneficiary and Program Research and Demonstrations (FKB6)

- Directs intramural and extramural research, demonstrations and evaluations on the Medicare and Medicaid programs and beneficiary populations that include, but are not limited to, maternal and child health, End Stage Renal Disease (ESRD), persons with Acquired Immune Deficiency Syndrome (AIDS), prescribed drugs, persons with cancer, persons with mental and physical chronic disease and disabilities, where the issues to be studied include, but are not limited to, health status and outcomes, information, eligibility, service use, access to care, coverage, expenditures and quality of care.
- Directs intramural and extramural studies on the impact of existing and new HCFA programs and payment systems on the beneficiaries.
- Directs intramural and extramural research, demonstrations and evaluations on ways to improve the decision-making process by which consumers select health insurance coverage, providers and treatments, and beneficiary satisfaction.
- Directs intramural and extramural research, demonstrations and evaluations related to new measures of quality of care.
- Directs intramural and extramural research, demonstrations and evaluations to support coverage policy for new and existing technology and procedures.
- Directs and performs the policy analyses of findings on issues that affect beneficiary populations and programs.

E.(1) Division of Health, Information and Outcomes (FKB61)

- Conducts intramural and extramural research, demonstrations and evaluations related to issues that affect the health status, outcomes, eligibility, access to, and use and costs of services for Medicare and Medicaid beneficiaries and special populations, such as, maternal and child health, persons with AIDS and cancer patients.
- Conducts intramural and extramural research, demonstrations and evaluations related to issues that affect the ESRD program.
- Conducts intramural and extramural research, demonstrations and evaluations related to beneficiary satisfaction.
- Conducts intramural and extramural studies on the impact of existing and new HCFA programs and payment systems on the beneficiaries.
- Conducts intramural and extramural research, demonstrations and evaluations on ways to improve the decision-making process by which consumers select health insurance coverage, providers and treatments.
- Carries out and analyzes the results of the Medicare Health Status Registry.
- Conducts intramural and extramural research, demonstrations and evaluations on health information for providers.
- Conducts intramural and extramural research, demonstrations and evaluations related to new measures of quality of care (not related to the aged and disabled).
- Conducts intramural and extramural research, demonstrations and evaluations to support coverage policy for new and existing technologies, procedures and pharmaceuticals.

• Analyzes the policy implications of findings on health, information, outcomes, access, coverage and quality.

E.(2) Division of Aging and Disability (FKB62)

• Conducts intramural and extramural research, demonstrations and evaluations on issues that affect program eligibility for populations that include persons with mental and physical chronic disease and disabilities.
• Conducts intramural and extramural research, demonstrations and evaluations on issues that affect coverage for populations that include persons with mental and physical chronic disease and disabilities.
• Conducts intramural and extramural research, demonstrations and evaluations on issues that affect cost of care for populations that include persons with mental and physical chronic disease and disabilities.
• Conducts intramural and extramural research, demonstrations and evaluations on issues that affect access to care for populations that include persons with mental and physical chronic disease and disabilities.
• Conducts intramural and extramural research, demonstrations and evaluations on issues that affect quality of health and long-term care services for populations that include persons with mental and physical chronic disease and disabilities.
• Conducts intramural and extramural research, demonstrations and evaluations related to new measures of quality of care for populations that include persons with mental and physical chronic disease and disabilities.
• Analyzes trends in long-term care programs and market characteristics.
• Analyzes the policy implications of findings on issues that affect aging and disability.

F. Office of Research and Demonstrations Support (FKB7)

• Directs the Fiscal Intermediary and Carrier activities for demonstrations.
• Directs the development, implementation and ongoing operations of demonstrations.
• Directs the design and development of payment methodologies for demonstrations, special cost reports and operational manuals.
• Directs the design, development and implementation of mainframe and personal computer (PC) based claims processing systems and collation of evaluation data.
• Directs the development of data programs to monitor and evaluate trends in Medicare/Medicaid and the health care system.
• Oversees programming and dataset technical assistance.
• Directs the control and support for PC's, local area networks (LAN's), computer communications and mainframe computer hardware/software packages.
• Participates with the Bureau of Data Management and Strategy (BDMS) in providing support and access to HCFA's data bases as required by research and demonstration activities.

F.(1) Division of Demonstrations Support (FKB71)

• Serves as Fiscal Intermediary and Carrier for demonstrations.
• Participates in the development, implementation and ongoing operations of demonstrations.
• Designs and develops payment methodologies when needed for demonstrations and studies, such as special cost reports, special operational manuals and participates in facilitating demonstrations.
• Designs, develops and implements mainframe and PC claims processing systems and collates data for evaluations.
• Conducts on-site audits of submitted costs reports and validates services rendered.

F.(2) Division of Data Systems Resources (FKB72)

• Develops, manages and maintains a variety of data programs to monitor and evaluate trends in Medicare/Medicaid and the health care system.
• Provides and participates in a variety of data support activities related to quality control and data verification.
• Provides programming and dataset technical assistance.
• Provides control and support for PCs, LAN, computer communications and mainframe computer hardware/ software packages.
• Participates with BDMS in providing necessary support and access to HCFA's data bases as required by research and demonstration activities.
• Coordinates ORD's participation in computer-based systems.
• Designs and develops a variety of analytic data bases.

Dated: March 8, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95–6885 Filed 3–20–95; 8:45 am]

BILLING CODE 4120–01–P

National Institutes of Health

National Cancer Institute; Opportunity for a Cooperative Research Agreement (CRADA) for the Scientific and Commercial Development of Diagnostic and/or Therapeutic Agents for Hyperpigmentary Lesions

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), seeks a pharmaceutical or cosmetic company that can effectively pursue the scientific and commercial generation and development of agents inhibiting pigmentation. The project is of scientific importance since it will characterize mechanisms whereby melanocyte function is compromised to produce hyperpigmented lesions. As such, this research will seek to provide insights into mechanisms responsible for clinically abnormal hyperpigmentation such as occurs in postinflammatory hyperpigmentation and other pigmentary diseases. NCI has successfully characterized the melanogenetic functions of several pigmentary genes that are important to the regulation of mammalian pigmentation. The NCI has produced a number of specific antibodies which recognize those gene products as well as a number of oligonucleotides and cDNAs whereby expression of their encoding genes can be quantitated. The selected sponsor will collaborate in a project aimed at using those probes to characterize melanocyte function in hyperpigmentary conditions and to develop agents useful commercially to down regulate melanogenic function.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Mark Noel or Bert Zbar (Telephone (301) 496–0477, Facsimile (301) 402–2117), Office of Technology Development, National Cancer Institute, Bldg 31, Room 4A49, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892

DATES: Proposals must be received at the above address by no later than May 22, 1995.

SUPPLEMENTARY INFORMATION:

''Cooperative Research and Development Agreement'' or ''CRADA'' means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The NCI is seeking a pharmaceutical or cosmetic company which can lend