procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 21, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: July 5, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–17832 Filed 7–19–95; 8:45 am]

BILLING CODE 4160–01–F

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 53 FR 8978, March 18, 1988) is amended to reflect the following reorganization in the Food and Drug Administration (FDA).

The Office of Training and Communications, Center for Drug Evaluation and Research (CDER) is being established to place stronger emphasis on professional training, and inter- and intra-Center communications. All training and communications functions have been centralized into the new Office.

Under section HF–B, Organization:

1. Delete the subparagraph Office of Management (HFN12), under the Office of the Center Director (HFN1), in its entirety and insert a new subparagraph reading as follows:

Office of Management (HFN12). Monitors the development and operation of planning systems for Center activities and resource allocations and advises the Center Director on Center administrative policies and guidelines and information systems and services.

Directs and counsels Center managers through program evaluation and technological forecasting.

Plans and directs Center operations for financial and personnel management, and office services.

Directs Center organization, management, and information systems.

Manages studies designed to improve processes and resource allocations in the Center.

Advises the Center on contract and grant proposals.

Provides coordination for receipt and distribution of initial drug applications and other related documents.

2. Insert the following new subparagraph, the Office of Training and Communications (HFN13), under the subparagraph titled Office of the Center Director (HFN1).

Office of Training and Communications (HFN13). Prepares, develops, and coordinates Center and Agency responses to drug-related requests under the Freedom of Information Act, Privacy Act, and other statutes.

Provides leadership and direction for all Center internal and external communications.

Plans, coordinates, and evaluates policies, procedures, and programs for the orientation and training of Center staff.

Provides scientific and technical resources and other library services to CDER staff in support of Center and Agencywide needs.

3. Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: July 10, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–17783 Filed 7–19–95; 8:45 am]

BILLING CODE 4160–01–M

National Institutes of Health

National Institute of Environmental Health Sciences: Opportunity for a Cooperative Research and Development Agreement (CRADA) for Development of Antibodies to the Cancer Metastasis Suppressor Gene KAI1

AGENCY: National Institute of Environmental Health Sciences, National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) seeks an agreement with a company(s) which can pursue commercial development of antibodies to the KAI1, a cancer metastasis suppressor gene (U.S. Patent Application Serial No. 08/430,225). The National Institute of Environmental Health Sciences has also determined that antibodies to this gene can be used in diagnosis of malignant cancers of the prostate and other tissues. A CRADA for the co-development of diagnostic antibodies will be granted to the awardee(s).

ADDRESSES: Proposals and questions about this opportunity may be addressed to Dr. J. Carl Barrett, NIEHS, Mail Drop C2–15, PO Box 12233, Research Triangle Park, NC 27709. Telephone (919) 541–2992; Fax (919) 541–7784; E-mail BARRETT@NIEHS.NIH.GOV.

DATE: Capability statements must be received by NIH on or before September 18, 1995.

SUPPLEMENTARY INFORMATION: The National Institute of Environmental Health Sciences has shown that the KAI1 gene can suppress metastasis of prostate cancer and is downregulated in human malignant prostate cancers. Therefore, it may be of use in distinguishing prostate cancers that will progress and be lethal from nonfatal cancers. The role of this gene in other cancers is currently under investigation. This protein is a transmembrane protein. Antibodies to the extracellular domain of the protein should detect its expression in tissue sections and tumor biopsies and be used in cancer diagnosis and prognosis.

The CRADA is for the development of antibodies to this protein and the development of cancer diagnostic tests.