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.

The awardee will have an option to negotiate an exclusive license to market and commercialize any new antibodies and tests developed within the scope of the research plan.

Role of the NIEHS

1. Provide expression vectors and recombinant protein as antigen for antibody production.
2. Work cooperatively with the company(s) to test antibodies produced for their ability to detect the KAI1 protein and determine its utility in cancer prognosis.

Role of the CRADA Partner

1. Assist in the isolation of recombinant proteins.
2. Develop antisera and monoclonal antibodies to the KAI1 gene.
3. Test the ability of antibodies to detect expression of the protein in histological sections.
4. Develop in cooperation with the NIEHS diagnostic tests for malignant cancers on the basis of KAI1 expression.

Selection criteria for choosing the CRADA partner(s) will include, but will not be limited to, the following:

1. Experience in monoclonal antibody and antisera production.
2. Capability to develop diagnostic tests for screening histological sections.

Dated: July 6, 1995.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 95–17779 Filed 7–19–95; 8:45 am]

BILLING CODE 4140–01–P

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to Mr. Arthur J. Cohn, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7735 ext 284; fax 301/402–0220). A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Ultraselective Opioidmimetic Peptides and Pharmacological and Therapeutic Uses Thereof

Lazarus, L.H., Salvadori, S., Temussi, P.A. (NIEHS)
Filed 30 Nov 94
Serial No. 08/347,531

Opioids and opioid receptors mediate a variety of effects in mammalian physiology including the production of analgesia, modification of the secretion of circulating peptide hormones, alteration of body temperature, depression of respiration, gastrointestinal function, and immune system activities. Opioids also have a wide range of therapeutic utilities, such as treatment of opiate and alcohol abuse, neurological diseases, neuropeptide or neurotransmitter imbalances, neurological and immune system dysfunctions, graft refections, pain control, shock and brain injuries. Various subclasses of opioid receptors are implicated in any particular physiological function or disease process. Accordingly, it would be desirable to have opioid drugs that exhibit specificity for one subclass of the receptor so as to avoid undesirable side effects during a therapeutic regimen. This invention provides novel opioidmimetic dipeptides, tripeptides and cyclic peptides which exhibit ultraselective specificity and potency for the δ opiate receptor. Additionally, methods of inducing analgesia and treating drug and alcohol addiction are provided. [*portfolio: Central Nervous System—Therapeutics*]

A Method Of Identifying CFTR-Binding Compounds Useful For Activating Chloride Conductance In Animal Cells

Pollard, H.B., Jacobson, K.B. (NIDDK)
Filed 22 Nov 94
Serial No. 08/343,714 (CIP of 07/952,965 issued as U.S. Patent 5,366,977)

Cystic fibrosis is the most common fatal genetic disease of Caucasians in the world today. The life expectancy of those affected with the disease is approximately 28 years. Cystic fibrosis affects some 30,000 children and young adults in the United States and approximately 24,000 children and young adults in Europe. Cystic fibrosis is caused by mutations in the cystic fibrosis transmembrane regulator (CFTR) gene. Chloride (Cl^-) and sodium transport across epithelial membranes of an individual afflicted with cystic fibrosis is abnormal. Many of the present efforts to combat the disease have focused on drugs that are capable of either activating the mutant CFTR gene product or otherwise causing additional secretion of Cl^- from affected cells. Antagonism of the A_1 adenosine receptor has been shown to result in stimulating Cl^- efflux from cystic fibrosis cells. Many of the drugs currently in use or under development function by antagonizing the A_1 adenosine receptor but lack specificity for the receptor and, thus, produce undesirable side effects. Likewise, antagonism of A_1 adenosine receptors probably will have an additional impact on an animal that is unrelated to the cystic fibrosis affliction. The present invention provides compositions and methods of identifying compositions that overcome these disadvantages, as well as methods of treating cystic fibrosis. The compounds provided activate impaired Cl^- conductance channels and exhibit high potency, low toxicity, and little or no specificity for adenosine receptors. [*portfolio: Internal Medicine—Therapeutics, pulmonary*]

Inhibiting Cell Proliferation By Inhibiting Mitogenic Activity Of Macrophage Migration Inhibitor Factor

Wistow, G.J., Paralkar, V. (NEI)
Filed 16 Nov 94
Serial No. 08/340,826

The control of cell growth is of interest in the understanding of normal physiological activity and pathological conditions such as cancer. Certain mechanisms of cell proliferation in cancer appear to mimic the growth-factor-induced mitogenic pathway. Peptide growth factors act by binding to receptors on the cell surface and inducing gene expression. This invention demonstrates that one of the genes induced by growth factors, macrophage migration inhibitory factor (MIF), is involved in cell proliferation and that inhibiting MIF expression in turn inhibits both peptide-growth-factor-induced and transformed cell proliferation. The invention provides methods for inhibiting cell growth by inhibiting the mitogenic activity of MIF in the cell. Such inhibition can be performed through providing the cell with a nucleic acid that inhibits MIF expression or through inhibiting MIF activity by hindering the binding of MIF to retinoblastoma protein. The invention also provides pharmaceutical compositions having an agent that inhibits the mitogenic activity of MIF in a cell and a pharmaceutically acceptable carrier. This invention would provide a means to inhibit growth factors in cancer cells *in vivo* and thereby prevent