

identification or classification of such specimens. \* \* \*

**Authority:** Section 122 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554).

(Catalog of Federal Domestic Assistance Program No. 93.779, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 15, 2004.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Statement of Organization, Functions and Delegations of Authority

This notice amends Part K of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KA, Office of the Assistant Secretary for Children and Families (OAS) as last amended October 16, 2001 (66 FR 52627) and Chapter KN, Office of Public Affairs (OPA) as last amended January 2, 1998 (63 FR 81-87). This notice announces the transfer of the Freedom of Information Act (FOIA) functions from the Office of the Executive Secretariat and places them in the Division of Public Information, Office of Public Affairs.

These Chapters are amended as follows:

#### I. Chapter KA, Office of the Assistant Secretary for Children and Families

A. Delete KA.20 Functions, Paragraph C in its entirety and replace with the following:

C. The Executive Secretariat (ExecSec) ensures that issues requiring the attention of the Assistant Secretary, Deputy Assistant Secretaries and/or executive staff are addressed on a timely and coordinated basis and facilitates decisions on matters requiring immediate action including White House, Congressional and Secretarial assignments. ExecSec serves as the ACF liaison with the HHS Executive Secretariat. It receives, assesses and controls incoming correspondence and assignments to the appropriate ACF component(s) for response and action

and provides assistance and advice to ACF staff on the development of responses to correspondence. ExecSec provides assistance to ACF staff on the use of the controlled correspondence system. ExecSec coordinates and/or prepares congressional correspondence, tracks development of periodic reports and facilitates Departmental clearances.

#### II. Chapter KN, Office of Public Affairs

A. Delete KN.00. Mission in its entirety and replace with the following:

KN.00 Mission. The Office of Public Affairs (OPA) develops, directs and coordinates public affairs and communications services for ACF. OPA serves as liaison with the Office of the Secretary, Office of Public Affairs in processing the Freedom of Information Act inquiries for ACF and coordinates hot line calls received by the Office of Inspector General and the Government Accountability Office relating to ACF operations and personnel. OPA provides leadership, direction and oversight in promoting ACF's public affairs policies, programs and initiatives. OPA also provides printing and distribution services for ACF.

B. Delete KN.20 Functions paragraph B, in its entirety and replace with the following:

B. The Division of Public Information (the Division) develops and implements public affairs strategies to achieve ACF program objectives in coordination with other ACF components. The Division coordinates news media relations strategy; responds to all media inquiries concerning ACF programs and related issues; develops fact sheets, news releases, feature articles for magazines and other publications on ACF programs and initiatives; and manages preparation and clearance of speeches and official statements on ACF programs. The Division coordinates regional public affairs policies and public affairs activities pertaining to ACF programs and initiatives. The Division Director serves as liaison to the Office of the Secretary, Office of Public Affairs in processing the Freedom of Information Act inquiries and coordinates hot line calls received by the Office of Inspector General and the Government Accountability Office relating to ACF operations and personnel.

Dated: December 14, 2004.

**Wade F. Horn,**

*Assistant Secretary for Children and Families.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency 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 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 the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Non-Small Cell Lung Cancer Cell Line H3255

Herbert K. Oie et al. (NCI)  
DHHS Reference No. E-028-2005/0—  
Research Tool  
*Licensing Contact:* Mojdeh Bahar; 301/435-2950; [baharm@mail.nih.gov](mailto:baharm@mail.nih.gov).

This invention, the H3255 cell line, was initiated from malignant cells isolated from the pleural effusion from a non-smoker Caucasian female. The cultured tumor cells, identified as Non-Small Cell Lung Carcinoma Cells (NSCLC), were found to have a mutation within the EGFR gene that made them very sensitive to certain growth inhibiting drugs, such as gefitinib (iresa). Cell lines sensitive to growth inhibitors could be used in the treatment of cancer as potential chemotherapeutic agents.

#### LRATlerin, Related Compounds and Methods of Use

Denise P. Simmons (NCI)  
U.S. Provisional Application No. 60/613,256 filed 27 Sep 2004 (DHHS Reference No. E-349-2004/0-US-01)  
*Licensing Contact:* Mojdeh Bahar; 301/435-2950; [baharm@mail.nih.gov](mailto:baharm@mail.nih.gov).

The invention discloses combinations of anti-tumor agents and anti-

proliferative peptides, methods for making such compounds, and methods for using these compounds for the treatment of hyper-proliferative diseases such as cancer or psoriasis. A current limitation on cancer therapy is that therapeutic agents may not target tumor cells specifically or enter the cells efficiently. A strategy that combines the therapeutic agent with a moiety that mediates cellular entry is one method to overcome this limitation. However, the efficacy of the therapeutic agent within the cells can be reduced by the linkage to the moiety that mediates cellular entry. The compounds of the current invention are designed to enter cells efficiently, and upon entry, to uncouple the therapeutic agent from the cellular targeting moiety.

Rottlerin, a protein kinase C inhibitor, selectively induces apoptosis of metastasized melanoma cells of epithelial morphology (DHHS Ref. No. E-311-2003), and is a potential therapeutic agent. Peptides derived from the known tumor suppressor genes H-Ha-Rev107 and H-TIG3, that are homologous to a peptide of LRAT (lecithin:retinol acyl transferase) cross the cell membrane and localize to the nucleus. These peptides, which inhibit the growth of melanoma cells (described in DHHS Ref. No. E-052-2002), could also serve as intracellular delivery agents.

The current invention discloses a novel composition of rottlerin and LRAT peptide (named LRATlerin). LRATlerin is designed so that the LRAT peptide can release the rottlerin upon cellular entry. LRATlerin has enhanced properties not exhibited by rottlerin or the peptide alone including the ability to induce apoptosis of primary site and metastasized tumor cells that are epithelioid or fibroblastoid, without apparent toxicity normal healthy cells. Thus, the compositions of the current invention have the potential to be highly effective therapies for proliferative diseases.

#### **Modulating Expression of the Metastasis Suppressor MxA**

Jane B. Trepel et al. (NCI)  
DHHS Reference No. E-257-2004/0-US-01 (U.S. Provisional Patent Application)

*Licensing Contact:* Mojdeh Bahar; 301/435-2950; [baharm@mail.nih.gov](mailto:baharm@mail.nih.gov).

The invention discloses compounds that could be used to inhibit metastases. The compounds of the current invention were discovered by high-throughput screening of a novel cell line engineered with a MxA reporter. The compounds could be used to treat metastatic cancers

including prostate and melanomas by increasing MxA expression.

MxA expression reduces cell motility and metastases in a mouse model. Cells expressing MxA produced smaller tumors in engrafted mice compared to controls. When injected into mouse spleens, cells expressing MxA showed a significantly delayed metastasis, and the mice survived significantly longer than controls. Expression of MxA reduced cellular motility of prostate cancer cell lines *in vitro* and reduced cellular motility and invasiveness of the highly metastatic melanoma cell line LOX.

Background information for this technology can be found in DHHS Reference No. E-292-2001.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

#### **Modified Myelin Basic Protein Molecules**

Michael J. Lenardo et al. (NIAID)  
DHHS Ref. No. E-033-1996/0-US-01  
*Licensing Contact:* Mojdeh Bahar; 301/435-2950; [baharm@mail.nih.gov](mailto:baharm@mail.nih.gov).

This invention is directed to compositions and methods for clinical assessment, diagnosis and treatment of Multiple Sclerosis (MS). The compositions are molecules related to the 21.5 kDa fetal isoform of human myelin basic protein (MBP), and include nucleic acids and polypeptides. The nucleic acids are useful in the efficient production of modified and unmodified MBP polypeptides and the polypeptides are useful for assaying T cells for responsiveness to MBP epitopes. They are further useful as therapeutic agents that act by inducing T cell responses, including apoptosis, as a means of treating MS.

#### **Modified Proteolipid Protein Molecules**

Michael J. Lenardo et al. (NIAID)  
DHHS Ref. No. E-128-1996/1-US-01  
*Licensing Contact:* Mojdeh Bahar; 301/435-2950; [baharm@mail.nih.gov](mailto:baharm@mail.nih.gov).

This invention is directed to compositions and methods for clinical assessment, diagnosis and treatment of Multiple Sclerosis (MS). The compositions are molecules related to the human proteolipid protein (PLP), and include nucleic acids and polypeptides. The nucleic acids are useful in the production of modified PLP polypeptides and the polypeptides are useful for assaying T cells for responsiveness to PLP epitopes. They are further useful as therapeutic agents that act by inducing T cell responses,

including apoptosis, as a means of treating MS.

Dated: December 15, 2004.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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BILLING CODE 4140-01-P

## **DEPARTMENT OF HOMELAND SECURITY**

### **Bureau of Customs and Border Protection**

#### **Proposed Collection; Comment Request Certificate of Compliance for Turbine Fuel Withdrawals**

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, Bureau of Customs and Border Protection (CBP) invites the general public and other Federal agencies to comment on an information collection requirement concerning the Certificate of Compliance for Turbine Fuel Withdrawals. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before February 22, 2005, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Bureau of Customs and Border Protection, Information Services Group, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C Washington, DC 20229.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Bureau of Customs and Border Protection, Attn. Tracey Denning, 1300 Pennsylvania Avenue NW., Room 3.2C, Washington, DC 20229, Tel. (202) 344-1429.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity