

request development of an acceptable residue detection method for an analysis of residues above any safe level established under part 530. The sponsor may be willing to provide the methodology in some cases, while in others, FDA, the sponsor, and perhaps

a third party (e.g., a State agency or a professional association), may negotiate a cooperative arrangement to develop the methodology. If no acceptable analytical method is developed, the agency would be permitted to prohibit extralabel use of the drug. The

respondents may be sponsors of new animal drugs, State or Federal government, or individuals.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 530.22 (b) | 2 | 1 | 2 | 4,160 | 8,320 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The Center for Veterinary Medicine (CVM) has not found circumstances to require the establishment of a safe level and subsequent development of an analytical methodology. However, CVM believes there will be instances when an analytical methodology will be required. Thus, we are estimating the reporting burden on one methodology being required annually.

Dated: January 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-2051 Filed 1-25-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: 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 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 contacting Marlene Shinn, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7056 ext. 285; fax: 301/402-0220; e-mail: shinnm@od.nih.gov. A signed Confidential Disclosure Agreement will

be required to receive copies of the patent applications.

Novel Vectors for Identifying Transgenic and Gene Targeting Animals

Dr. Dan Buchholz et al. (NICHD)

DHHS Reference No. E-319-01/0—
Research tool

Advances in vertebrate genetics have led to the development of gene knockout animals that allow for the study of gene function and transgenic analysis. This has also encouraged the development of gene-based therapies through introduction of exogenous genes to enhance and/or replace dysfunctional or missing genes. Yet, although the advances have been many, the analysis remains complicated with tedious screening of animals containing the desired genotype.

The NIH announces a double-promoter plasmid that carries a transgene under the control of any preferred promoter and the Green Fluorescent Protein (GFP) under the control of the eye-specific crystalline-promoter for transgenesis. This construct creates a green fluorescence in the eyes of the transgenic animals thus allowing for easy identification. Companies that work in the transgenic or gene targeting areas would find this plasmid useful in quickly and efficiently identifying desired transgenic animals with biological functionality of their gene of interest.

Combined Inhibition of Phosphodiesterase-4 (PDE-4) and Phosphodiesterase-3 (PDE-3) as a Therapy for Th1 Mediated Autoimmune Diseases

Dr. Bibiana Bielekova et al. (NINDS)

DHHS Reference Nos. E-077-00/0 filed 22 Dec 2000 and E-077-00/1 filed 21 Dec 2001

Hyperactive Th1-mediated immune responses are thought to be involved in

the pathogenesis of many autoimmune diseases, including rheumatoid arthritis, diabetes, inflammatory bowel disease, vitiligo, and multiple sclerosis among others. Immune cells are known to produce primarily two classes of phosphodiesterases (PDE), the PDE4 and the PDE3 classes. Inhibitors of these PDEs have been shown to down-regulate the expression or production of Th1 cytokines and have either no effect or augment the production of Th2 cytokines, therefore making them good candidates for the treatment of Th1-mediated autoimmune diseases.

The NIH announces a new technology wherein PDE-4 and PDE-3 inhibitors are used in combination and a synergistic enhancement of therapeutic activity is achieved. This results in a more potent immunomodulatory effect on the immune cells and could lead to the administration of lower dose rate of the inhibitors. This new form of treatment will alleviate side effects through the use of a lower dose rate for each and will make for a more effective therapy.

Dated: January 17, 2002.

Jack Spiegel,

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

[FR Doc. 02-2029 Filed 1-25-02; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: 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 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.

HGC-1, A Gene Encoding a Member of the Olfactomedin-Related Protein Family

Griffin P. Rodgers, Wen-Li Liu, Jiachang Zhang (NIDDK)

DHHS Reference No. E-166-01/0 filed 07 Dec 2001

Licensing Contact: Kai Chen; 301/496-7736 ext. 247; e-mail: chenk@od.nih.gov

The current technology embodies a newly identified gene, Human Granulocyte Colony-Stimulating Factor-Stimulated-Clone-1 (hGC-1), that has been cloned and characterized, and its protein sequence has been deduced. The gene is expressed in the bone marrow, prostate, small intestine, colon, and stomach, and has been mapped to chromosome 13 in a region that contains a tumor suppressor gene cluster. The gene is found to be selectively present in normal human myeloid lineage cells and is believed to play a role in allowing lymphocytes to differentiate properly. It is believed that the gene may be used as a selective marker for human prostate cancer, multiple myeloma, B-cell chronic lymphocytic leukemia and other types of cancer and can be used diagnostically as well as in therapeutic screening activities.

Mitochondrial Topoisomerase I

Yves Pommier and Hong-Liang Zhang (NCI)

DHHS Reference No. E-099-01/0 filed 16 Feb 2001

Licensing Contact: Matthew Kiser; 301/496-7056 ext. 224; e-mail: kiserm@od.nih.gov

The subject technology is an isolated or purified nucleic acid molecule consisting essentially of a nucleotide sequence encoding mitochondrial topoisomerase I (top1mt), a variant

top1mt, or a fragment of either of the foregoing, an isolated or purified nucleic acid molecule consisting essentially of a nucleotide sequence that is complementary to a nucleotide sequence encoding top1mt, a variant top1mt, or a fragment of either of the foregoing, a vector comprising such an isolated or purified nucleic acid molecule, a cell comprising such a vector, an isolated or purified polypeptide molecule consisting essentially of an amino acid sequence encoding top1mt or a variant top1mt, a conjugate comprising such an isolated or purified polypeptide molecule and a cell-surface targeting moiety, a hybridoma cell line that produces a monoclonal antibody that is specific for an aforementioned isolated or purified polypeptide molecule, the monoclonal antibody produced by the hybridoma cell line, a polyclonal antiserum raised against an aforementioned isolated or purified polypeptide molecule, a method of altering the level of top1mt in a cell, and a method of identifying an inhibitor or an activator of top 1 mt.

Dated: January 17, 2002.

Jack Spiegel,

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

[FR Doc. 02-2030 Filed 1-25-02; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of 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 a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and

personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Fogarty International Center Advisory Board.

Date: February 5, 2002.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: Report of the Director on updates and an overview of new FIC programs and initiatives. In addition, a discussion of CDC plans, present and future, for international programs and global health concerns.

Place: Lawton Chiles International House, 16 Center Drive, (Building 16), Bethesda, MD 20892.

Closed: 1:00 PM to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Lawton Chiles International House, 16 Center Drive, (Building 16), Bethesda, MD 20892.

Contact Person: Irene W. Edwards, Information Officer, Fogarty International Center, National Institutes of Health, Building 31, Room B2C08, 31 Center Drive MSC 2220, Bethesda, MD 20892, 301-496-2075.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Information is also available on the Institute's/Center's home page: www.nih.gov/fic/about/advisory.html, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: January 18, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-2025 Filed 1-25-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of 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.