

The reporting burden for § 100.1(d) is insignificant because petitions for exemption from preemption are seldom submitted by States requesting the agency grant an exemption from preemption by labeling requirements based upon certain sections of the act. Over the last 3 years, FDA has not received any preemption petitions. Since the enactment of section 403A(b) of the act as part of the Nutrition Labeling and Education Act of 1990, FDA has received only eight petitions for seeking exemption from preemption. Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403A(b) of the act.

Dated: August 16, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy,
Planning and Legislation.

[FR Doc. 99-21581 Filed 8-19-99; 8:45 am]

BILLING CODE 4160-01-F

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.

Surface Coating for Hot-Melt Adhesive Films

John I. Peterson, Tristan Gorrindo (ORS), DHHS Reference No. E-015-99/0 filed 10 May 1999.

Licensing Contact: John Fahner-Vihtelic; 301/496-7735 ext. 270; e-mail: jf36z@nih.gov.

The present application describes a method and apparatus for applying thin-film coatings to poly(ethylene/vinyl acetate, CAS24937-78-8) (EVA) hot-melt layers used in Laser Capture Microdissection (LCM). These methods result in the placement of a hard, non-adhering surface on the EVA layer. The placement of this layer overcomes the problems associated with nonspecific pickup of tissue. Analysis errors in tissue samples captured by laser melting are easily prevented, and using various brush-off or wash-off techniques the removal of undesired tissue material from EVA with thin-film coatings is easily accomplished. Additional advantages include the protection of the hard surface against ambient humidity and temperature variations that adversely affect performance. A desirable coating is one that is a water or water-ethanol solution since it does not deform the EVA surface. Three materials have been tested and are acceptable for this application.

A Method of Preventing Tumor Metastasis

S Rong, G Vande Woude, DL Faletto, I Tsarfaty, M Oskarsson (NCI),
Serial No. 09/248,901 filed 12 Feb 1999.

Licensing Contact: Susan S. Rucker;
301/496-7056 ext. 245; e-mail:
sr156v@nih.gov

This application generally relates to signal transduction involving hepatocyte growth factor/scatter factor (HGF/SF) and its receptor the *met* proto-oncogene. *In vitro* experiments have indicated that some tumors, such as sarcomas, exhibit metastatic behavior due to inappropriate HGF/SF signaling. The application describes a method whereby this signaling can be inhibited by a substance such as an HGF/SF variant, an HGF/SF mimetic or an antibody or antibody fragment that prevents HGF/SF from binding to *met*.

Several related cases are also available for licensing: U.S. Patent 5,871,959 issued 2/16/1999 entitled "A Method of Producing HGF/SF and Related Cell Lines" and U.S. Patent 5,648,273 issued 7/15/1997 entitled "Hepatic growth factor receptor is the MET proto-oncogene".

Expressed Sequence Tags of Genes Expressed in Drosophila Testes

Brian Oliver, Justen Andrews, Jining Lu (NIDDK)

DHHS Reference No. E-023-99/0.
Licensing Contact: Peter Soukas, 301/496-7056 ext. 268; e-mail:
ps193c@nih.gov.

This unpatented invention describes the generation of high quality Expressed Sequence Tags (ESTs) of genes expressed in *Drosophila* testes obtained through ongoing sequencing. Approximately sixty percent (60%) of the generated ESTs have no significant homology to existing *Drosophila* EST sets. Thus, this invention represents a valuable addition to the *Drosophila* unigene set. Additionally, approximately forty-three percent (43%) of these ESTs have no significant similarity to sequences to any other organism in public databases, representing possibly previously unidentified genes.

Approximately 3000 sequence reads have been submitted to dbEST at the present time. The ESTs were prepared from a library derived from poly-A⁺ RNA isolated from 700 y* w^{67c1} 1-5 day post-eclosion testis. cDNA was cloned in the Stratagene Uni-Zap XR vector according to the manufacturer's instructions. The primary unamplified library contained 8×10^6 plaque forming units (pfu). The library was amplified once (1×10^6 pfu yielded 1.75×10^{12} pfu). There are no NIH patent rights associated with this invention; it is available for commercialization through a Biological Materials License Agreement.

Fibroblast Growth Factor Receptor Activating Gene 1 (FRAG1), Related Proteins and Methods

MV Lorenzi (NCI), T Miki (NCI)
Serial No. 09/202,548 filed 15 Dec 98
claiming priority to PCT/US97/10660
filed 18 Jun 97 and 60/020,009 filed
18 Jun 96

Licensing Contact: Susan S. Rucker;
301/496-7056 ext. 245; e-mail:
sr156v@nih.gov

These applications describe the identification, isolation and cloning of the human gene named Fibroblast Growth Factor Receptor Activating Gene 1 (FRAG1) as well as its rat homolog. A full length clone of the human FRAG1 was deposited and the partial sequence (about 90%) is disclosed. The complete sequence of the rat homolog is disclosed.

The gene for FRAG1 encodes a protein which activates the known growth factor receptor, Fibroblast Growth Factor Receptor 2 (FGFR2).

FRAG1, when fused to FGFR2, leads to a transformed phenotype when transfected into cells and enhanced levels of phosphorylation/activation of FGFR2. The FGFR2-FRAG1 fusion protein was isolated from an osteosarcoma. Products derived from the FRAG1 cDNA, protein or antibodies which recognize the FRAG1 antigen are likely to be useful as diagnostics, therapeutics and research reagents.

This work has appeared, in part, in Lorenzi, MV, et al. "FRAG1, a gene that potentially activates fibroblast growth factor receptor by C-terminal fusion through chromosomal rearrangement" PNAS, USA 93(17): 8956-61 (Aug. 20, 1996).

Spontaneous Breathing Apparatus and Method

Theodor Kolobow (NHLBI)
Serial No. 08/933,003 filed 18 Sep 1997.
Licensing Contact: Girish Barua; 301/496-7056 ext. 263; e-mail: gb18t@nih.gov

A novel assisted breathing system and method has been developed to greatly decrease/eliminate work of breathing, and is under the total control of a patient.

The system includes a minitracheostomy tube, a reverse thrust gas insufflation catheter introduced through a special minitracheostomy tube to deliver well humidified air/oxygen to near the carina, and a threshold valve to limit airway plateau pressure. Inspiration is effected through spontaneous closing of the glottic opening, while expiration follows opening of the glottis. Such breathing is under the exclusive, spontaneous control of a patient to determine respiratory rate and tidal volumes. Lung inflation is hence passive, and accounts for the greatly decreased (even zero) work of breathing. Speech, cough and swallowing remain unimpeded.

Dated: August 16, 1999.

Jack Spiegel,

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

[FR Doc. 99-21706 Filed 8-19-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 National Advisory Neurological Disorders and Stroke Council.

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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosures of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.
Date: September 23-24, 1999.

Open: September 23, 1999, 8:30 AM to 3 PM.

Agenda: Report by the Director, NINDS; Report by the Associate Director for Extramural Research; and other administrative and program developments.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Closed: September 23, 1999, 3 PM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Closed: September 24, 1999, 8:30 AM to 12 PM.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Constance W. Atwell, Associate Director for Extramural Research, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Suite 3309, MSC 9531, Bethesda, MD 20892-9531, (301) 496-9248.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 13, 1999.

LaVerne Y. Stringfield,
Committee Management Officer, NIH.

[FR Doc. 99-21701 Filed 8-19-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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.

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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel—Vancomycin Resistant S. aureus in Dialysis Patients.

Date: August 30, 1999.

Time: 9:30 am to 10:30 am.

Agenda: To review and evaluate grant applications.

Place: NIAID, NIH (Room 2148), 6700-B Rockledge Drive, MSC 7610, Bethesda, MD 20892-7610 (Telephone Conference Call).

Contact Person: Dianne E. Tingley, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2220, 6700-B Rockledge Drive, MSC 7610, Bethesda, MD 20892-7610, 301-496-2550.

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 13, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy, NIH.

[FR Doc. 99-21702 Filed 8-19-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as