

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of Respondents	Number of Responses per Respondent	Total annual responses	Average burden per response	Total hours
Request for reduction of fees collected under section 743 of the FD&C Act	235	1	235	2	470

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

FDA estimates that 510 facilities will be subject to the reinspection and the recall fees under section 743 of the FD&C Act. Of these facilities, we estimate that 46 percent will be small businesses with annual gross sales under \$250,000. Therefore, 46 percent of 510 equals to 235 respondents. Each respondent will submit 1 request for reduction of fees. Total annual responses are 235. The average burden is 2 hours, giving a total of 470 hours annual burden.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30471 Filed 11–22–11; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Centers for Disease Control and Prevention

Statement of Delegation of Authority

I hereby delegate to the Administrator, Health Resources and Services Administration (HRSA), and the Director, Centers for Disease Control and Prevention (CDC), with authority to redelegate, the authority vested in the Secretary under Title III, Part P, Section 399T (42 U.S.C. 280g–8), titled “Support for Patients Receiving a Positive Diagnosis of Down Syndrome or Other Prenatally or Postnatally Diagnosed Conditions,” of the Public Health Service Act, as amended, insofar as such authority pertains to the functions of HRSA and CDC, respectively. HRSA and CDC will coordinate and collaborate with each other and with the National Institutes of Health, as appropriate, in implementing this authority.

This delegation excludes the authority to issue regulations, to establish advisory committees and councils, and appoint their members, and shall be exercised in accordance with the Department’s applicable policies, procedures, and guidelines.

I hereby affirm and ratify any actions taken by the Administrator, HRSA, the Director, CDC, or other HRSA and CDC officials, which involve the exercise of these authorities prior to the effective date of this delegation.

This delegation is effective upon date of signature.

Dated: November 14, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–30411 Filed 11–23–11; 8:45 am]

BILLING CODE 4165–15–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, 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.

Genetically Engineered Mouse Model for Use as an Alternative Screening Method for Evaluating P-glycoprotein (P-gp) Substrate Toxicity in Avermectin-sensitive Dogs

Description of Technology: A pitfall to avermectins is central nervous system

(CNS) toxicities in herding dogs. As a result, all new avermectins must be tested in a “Collie Safety Study” to determine the degree of CNS toxicity. The toxicity is due to a 4 base pair mutation in the ATP-binding cassette, sub-family B member 1 (ABCB1) gene. This gene encodes for the P-glycoprotein (P-gp) that affects absorption, distribution and elimination of certain drugs. Researchers at FDA have developed an alternate animal model that includes two transgenic mouse models, one containing the mutant form of the canine ABCB1 gene (Yancy 1 line) and the other containing the canine wild-type gene (Yancy 2 line). The paired mouse system can be utilized to assess the safety of avermectins and other canine drugs by determining the toxicity to canines with the mutated form of the ABCB1 gene. Ivermectin, a derivative of the avermectin family of heartworm drugs used to treat and control parasitic infections, was used to verify this mouse model. This technology will enhance the population predictions derived from clinical safety data and serve to reduce the use of dogs in avermectin derivative safety studies that are part of the Investigational New Animal Drug (INAD) approval process.

Potential Commercial Applications: Drug screening technology to assess the toxicity of canine drugs to canines with the mutated form of the ABCB1 gene.

Competitive Advantages: Use as an alternative in vivo model to canines for assessment of drug safety in the presence of the ABCB1 mutation.

Development Stage: In vivo data available (animal).

Inventor: Haile F. Yancy (FDA).

Publication: Orzechowski K, *et al.*, in press Am J Vet Res.

Intellectual Property: HHS Reference No. E–292–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Jaime Greene; (301) 435–5559; *greenejaime@mail.nih.gov.*

Collaborative Research Opportunity:

The FDA Center for Veterinary Medicine is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or

commercialize this alternative mouse model. For collaboration opportunities, please contact Haile F. Yancy at haile.yancy@fda.hhs.gov or (301) 210-4096.

Treatment of Tuberculosis—Adjuvant Therapies To Increase the Efficiency of Antibiotic Treatments

Description of Technology: There is growing evidence that resistance to *Mycobacterium tuberculosis* infection is governed in large part by the regulation of host cell death. Lipid mediators called eicosanoids are thought to play a central role in this process. The subject invention is a novel method of enhancing the efficacy of antibiotic treatments for *Mycobacterium tuberculosis* infection by co-administering an inhibitor of 5-lipoxygenase and a COX-2 dependent prostaglandin. Inhibition of 5-lipoxygenase and treatment with prostaglandin E2 results in alteration of the eicosanoid balance. The synergistic effects of altering the eicosanoid balance and treatment with antibiotics is believed to result in more efficient reduction of the bacterial burden and thus, the period of antibiotic administration and antibiotic dosage could potentially be reduced. In vivo data from mouse models can be provided upon request.

Potential Commercial Applications: The subject invention can be used as an adjuvant therapy for existing antibiotic treatment regimens against tuberculosis.

Competitive Advantages: The disclosed method can be applied to increase the efficacy of existing antibiotic treatments for tuberculosis, potentially reducing both the duration and dosage of the antibiotic treatment.

Development Stage:

- Early-stage.
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Katrin D. Mayer, Bruno Bezerril D. Andrade, F. Alan Sher, and Daniel L. Barber (NIAID).

Intellectual Property:

- HHS Reference No. E-189-2011/0—U.S. Provisional Patent Application No. 61/515,229 filed 04 Aug 2011.
- HHS Reference No. E-189-2011/1—U.S. Provisional Patent Application No. 61/515,237 filed 04 Aug 2011.

Licensing Contact: Kevin W. Chang, Ph.D.; (301) 435-5018; changke@mail.nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or

commercialize adjuvant therapy for antibiotic treatment regimens against tuberculosis. For collaboration opportunities, please contact Katrin Mayer, Ph.D. at mayerk@niaid.nih.gov or (301) 594-8061.

DPEP1 and TPX2 as Prognostic Biomarkers for Pancreatic Ductal Adenocarcinoma

Description of Technology: Scientists at NIH have developed prognostic biomarkers and a candidate therapeutic target for pancreatic ductal adenocarcinoma (PDAC). PDAC is a devastating cancer, and patients have an average survival of six months. The 5-year survival for PDAC patients is only 6%. This high lethality in pancreatic cancer is due to the late diagnosis and lack of any effective treatment. Greater than 80% of patients are diagnosed in an advanced stage of the disease. The instant invention is a discovery of biomarkers to make prognostic conclusions about the progression of PDAC by measuring the expression of DPEP1 and TPX2. Patients with decreased DPEP1 and increased TPX2 expression have poorer outcome. Furthermore, DPEP1 and TPX2 are controlled by the MAPK pathway. A MAPK inhibitor can be used as a treatment because it can lead to increased DPEP1 and decreased TPX2 expression, which is associated with better survival.

Potential Commercial Applications

- Prognostic biomarker to identify high-risk patients.
- Identification of MAPK inhibitor(s) altering DPEP1 and TPX2 expression.

Competitive Advantages

- Combination of measuring DPEP1 and TPX2 expression levels results in improved prognosis prediction.
- Development of expression level patterns during tumorigenesis that are representative of PDAC.

Development Stage: In vivo data available (human).

Inventors: Syed P. Hussain and Geng Zhang (NCI).

Publication: DPEP1 and TPX2 as Independent Predictors of Cancer-Specific Mortality in Pancreatic Ductal Adenocarcinoma, submitted April 2011.

Intellectual Property: HHS Reference No. E-171-2011/0—U.S. Patent Application No. 61/512,302 filed 27 July 2011.

Licensing Contact: Uri Reichman, Ph.D., MBA; (301) 435-4616; reichmau@mail.nih.gov.

AAV Mediated CTLA-4 Gene Transfer To Treat Sjögren's Syndrome

Description of Technology: Sjögren's syndrome is an autoimmune disease that affects over 2 million Americans, primarily over the age of 40. One of the major outcomes of Sjögren's syndrome is xerostomia (dry mouth) that is caused by immune system attack on moisture producing salivary glands. Researchers at the National Institute of Dental and Craniofacial Research have developed a therapy that alleviates xerostomia in a murine model of Sjögren's syndrome. This technology consists of a local delivery of adeno-associated virus (AAV) mediated cytotoxic T-lymphocyte antigen 4 Immunoglobulin-G (CTLA4IgG) fusion protein to salivary glands. The system effectively blocks CTLA4 ligand interactions with T cell surface receptors, resulting in immune suppression and reversal of autoimmune-related xerostomia. Targeted delivery of the AAV-CTLA4-IgG system makes this invention a novel therapeutic for the prevention of xerostomia-associated pain and discomfort caused by Sjögren's syndrome.

Potential Commercial Applications: Prevention of salivary gland destruction and xerostomia development in patients with Sjögren's syndrome.

Competitive Advantages

- Current treatments temporarily reduce the discomfort of xerostomia but do not prevent the deleterious effects of this disorder.
- AAV gene transfer to salivary glands is highly efficient.
- AAV therapy is safe and noninflammatory.

Development Stage

- In vitro data available.
- In vivo data available (animal).

Inventors: Hongen Yin and John Chiorini (NIDCR).

Publications

1. Zheng C, *et al.* Assessment of the safety and biodistribution of a regulated AAV2 gene transfer vector after delivery to murine submandibular glands. *Toxicol Sci.* 2011 Sep;123(1):247-255. [PMID: 21625005]
2. Kanaya K, *et al.* Combined gene therapy with adenovirus vectors containing CTLA4Ig and CD40Ig prolongs survival of composite tissue allografts in rat model. *Transplantation.* 2003 Feb 15;75(3):275-281. [PMID: 12589145]
3. Genovese MC, *et al.* Abatacept for rheumatoid arthritis refractory to tumor necrosis factor alpha inhibition. *N Engl J Med.* 2005 Sep 15;353(11):1114-1123. [PMID: 16162882]

Intellectual Property: HHS Reference No. E-087-2011/0—U.S. Provisional Application No. 61/476,168 filed 15 April 2011.

Licensing Contact: Jaime Greene; (301) 435-5559; greenejaime@mail.nih.gov.

Collaborative Research Opportunity: The NIDCR is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact David Bradley at bradleyda@nidcr.nih.gov.

Dated: November 18, 2011.

Richard U. Rodriguez,

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

[FR Doc. 2011-30357 Filed 11-23-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Interagency Breast Cancer and Environmental Research Coordinating Committee.

The meeting will be open to the public, 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.

Name of Committee: Interagency Breast Cancer and Environmental Research Coordinating Committee.

Date: December 13, 2011.

Time: 3 p.m. to 5 p.m.

Agenda: The purpose of the meeting is to continue the work of the Research Translation, Dissemination, and Policy Implications Subcommittee as it addresses a broad set of objectives related to the overall mandate of the IBCERC. The meeting agenda will be available on the Web at <http://www.niehs.nih.gov/about/orgstructure/boards/ibcercc/>.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709. (This meeting will be conducted remotely. To attend the meeting, please RSVP via email to ibcercc@niehs.nih.gov at least 10 days in advance and instructions for joining the meeting will be provided.)

Contact Person: Gwen Collman, Ph.D., Director, Division of Extramural Research &

Training, National Institutes of Health, Nat. Inst. of Environmental Health Sciences, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709, (919) 541-4980, collman@niehs.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: November 17, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-30352 Filed 11-23-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel, Member Conflict: AIDS/HIV.

Date: December 13-14, 2011.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact: Kenneth A Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106,

MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuckk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Diabetes and Obesity.

Date: December 14, 2011.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Krish Krishnan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435-1041, krishnak@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 17, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-30348 Filed 11-23-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Cargo Manifest/Declaration, Stow Plan, Container Status Messages and Importer Security Filing

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information: 1651-0001.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Cargo Manifest/Declaration, Stow Plan, Container Status Messages and Importer Security Filing. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13).

DATES: Written comments should be received on or before January 24, 2012, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229-1177.