TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
520(m)(6)(A)(ii)	3	1	3	50	150
520(m)(6)(A)(iii)	1	1	1	100	100
520(m)(6)(C)	5	1	5	100	500
Total					1,250

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

FDA based these estimates on the number of original HDE applications that the Center for Devices and Radiological Health (CDRH) received in the period between October 1, 2004, and September 30, 2007. During that time, CDRH received 16 original HDE applications or about 5 per year.

FDA estimates that for each year, CDRH will receive five HDE applications and that three of these applications will be indicated for pediatric use. One HDE holder will notify the agency that the number of devices distributed in the year has exceeded the ADN and five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease of condition.

The draft guidance refers also to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in part 814, subparts A, B, and C have been approved under OMB control number 0910–0231; the collection of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in part 814, subpart H have been approved under OMB control number 0910–0332; and the collection of information requirements in 21 CFR 10.30 have been approved under OMB control number 0910–0183.

Dated: September 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23521 Filed 9–29–09; 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, 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.

Immortalized Transformed Lymphoblastoid Cell Lines From Patients with François-Neetens Mouchetée Fleck Corneal Dystrophy (CFD)

Description of Invention: Researchers at the National Eye Institute, NIH, have made available a set of immortalized transformed lymphoblastoid cell lines created from human T-lymphocytes obtained from patients with François-Neetens Mouchetée Fleck Corneal Dystrophy (CFD). The cells were transformed with defective Epstein-Barr virus using established methods.

CFD is a rare, autosomal dominant corneal dystrophy characterized by numerous small white flecks scattered in all layers of the stroma. CFD has been associated with mutations in the PIP5K3 protein, which is important for post-Golgi vesicle processing.

Applications:

- Useful in the study of proteins expressed by lymphocytes, including in some cases the protein encoded by the mutant gene KCNJ13.
- Useful as a renewable source of DNA for genetic studies related to CFD or the PIP5K3 protein.

Inventors: J. Fielding Hejtmancik and Xiaodong Jiao (NEI).

Relevant Publications:

1. S Li *et al.* Mutations in PIP5K3 are associated with François-Neetens mouchetée fleck corneal dystrophy. Am J Hum Genet. 2005 Jul;77(1):54–63.

2. X Jiao *et al.* Genetic linkage of Francois-Neetens fleck (mouchetée) corneal dystrophy to chromosome 2q35. Hum Genet. 2003 May; 112(5–6):593–599.

Patent Status: HHS Reference No. E–270–2009/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a biological material license.

Licensing Contact: Patrick P. McCue, PhD; 301–435–5560; *mccuepat@mail.nih.gov.*

Novel Chemoattractant-Based Toxins to Improve Vaccine Immune Responses for Cancer and Infectious Diseases

Description of Invention: Cancer is one of the leading causes of death in United States and it is estimated that there will be more than half a million deaths caused by cancer in 2009. A major drawback of the current chemotherapy-based therapeutics is the cytotoxic side-effects associated with them. Thus there is a dire need to develop new therapeutic strategies with fewer side-effects. Immunotherapy has taken a lead among the new therapeutic approaches. Enhancing the innate immune response of an individual has been a key approach for the treatment against different diseases such as cancer and infectious diseases.

This technology involves the generation of novel chemoattractant toxins that deplete the T regulatory cells (Treg) or other immunosuppressive or hyperactivated cells locally. Treg controls activation of immune responses by suppressing the induction of adaptive immune responses, particularly T cell responses. Immunosuppressive cells such as tumor infiltrating macrophages, regulatory T cells, regulatory B cells, or NKT and other cells down regulate antitumor immune responses. The chemoattractant toxins consist of a toxin moiety fused with a chemokine receptor ligand, such as chemokines and various chemoattractants, that enables specific targeting and delivery to the regulatory cells. This technology is advantageous over the more harmful antibodies and chemicals that are currently used for the systemic depletion of regulatory cells. The current technology can be used therapeutically in a variety of ways. They can be used together with vaccines to increase efficacy of the vaccine for the treatment of cancer, and can be used to locally deplete Treg, Bregs, or other immunosuppressive cells to induce cytolytic cell responses at the tumor site or to eliminate chronic infectious diseases such as HIV and tuberculosis.

Applications:

• New chemoattractant based toxins targeted towards Treg cells.

• New chemoattractant based toxins targeted towards immunosuppressive B cells, NKT and macrophages.

• New chemoattractant based toxins targeted towards local depletion of hyperactivated CD4 T cells to treat autoimmune diseases.

• Chemoattractant based toxins depleting Treg cells or other immunosuppressive cells causing enhanced vaccine immune responses.

• Novel immunotherapy by increasing vaccine efficacy against cancer and infectious diseases.

Development Status: The technology is currently in the pre-clinical stage of development.

Market:

• The technology platform involving novel chemo-attractant based toxins can be used to improve vaccine immune responses.

• The technology platform has an additional market in treating several other clinical problems such as autoimmune diseases.

Inventors: Arya Biragyn (NIA), Dolgor Bataar (NIA), *et al.*

Related Publications:

1. D Baatar, P Olkhanud, D Newton, K Sumitomo, A Biragyn. CCR4-expressing T cell tumors can be specifically controlled via delivery of toxins to chemokine receptors. J Immunol. 2007 Aug 1;179(3):1996–2004.

2. D Baatar, P Olkhanud, K Sumitomo, D Taub, R Gress, A Biragyn. Human peripheral blood T regulatory cells (Tregs), functionally primed CCR4+ Tregs and unprimed CCR4- Tregs, regulate effector T cells using FasL. J Immunol. 2007 Apr 15;178(8):4891–900.

3. M Coscia, A Biragyn. Cancer immunotherapy with chemoattractant peptides. Semin Cancer Biol. 2004 Jun; 14(3):209–218.

4. R Schiavo *et al.* Chemokine receptor targeting efficiently directs antigens to MHC class I pathways and elicits antigen-specific CD8+ T-cell responses. Blood 2006 Jun 15; 107(12):4597–4605.

Patent Status: U.S. Patent Application No. 11/992,880 filed 28 Mar 2008 (HHS Reference No. E–027–2005/0–US–06)

Licensing Status: Available for licensing.

Licensing Contact: Patrick P. McCue, PhD; 301–435–5560; *mccuepat@mail.nih.gov.*

Collaborative Research Opportunity: The Immunotherapeutics Unit, National Institute on Aging, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Chemotoxin technology for clinical use or as a laboratory tool for depletion of cells. Please contact Nicole Darack, PhD at 301–435–3101 or *darackn@mail.nih.gov* for more information.

Novel Agents Exhibiting Cytotoxicity Against Human Tumor Cell Lines

Description of Invention: Researchers at the National Cancer Institute have developed novel agents that inhibit the growth of several human tumor cell lines. The new compounds are phenyl maleimides, some of which show cytotoxicity against human liver cancer cells in vitro in the low micromolar range.

Applications:

• Therapeutics for treating a broad range of cancers.

• Use as pharmacologic probes for specific biochemical pathways.

Advantages:

• Demonstrated selective inhibition for cancer cells vs. untransformed cells *in vitro* and *in vivo.*

• Potent growth inhibition of several human tumor cell lines.

Development Status: Pre-clinical stage of development.

Market: Cancer therapeutics.

Inventors: Christophr J. Michejda and Wei Yao (NCI) *et al.;* Terrence R. Burke Jr. (NCI).

Relevant Publication: S Kar, M Wang, W Yao, CJ Michejda, BI Carr. PM–20, a novel inhibitor of Cdc25A, induces extracellular signal-regulated kinase 1/2 phosphorylation and inhibits hepatocellular carcinoma growth in vitro and in vivo. Mol Cancer Ther. 2006 Jun; 5(6):1511–1519.

Patent Status: U.S. Patent No. 7,504,430 issued 17 Mar 2009 (HHS Reference No. E–110–2004/0–US–06).

Licensing Status: Available for licensing.

Licensing Contact: Patrick P. McCue, PhD; 301–435–5560; *mccuepat@mail.nih.gov.*

Dated: September 21, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–23590 Filed 9–29–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

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 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 Biomedical Imaging and Bioengineering Special Emphasis Panel.

Date: November 19, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John K. Hayes, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Suite 959, Democracy Two, Bethesda, MD 20892, 301–451–3398, *hayesj@mail.nih.gov.*